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Acquired brain injury

Psychological sequelae and holistic approaches to intervention

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Acquired brain injury: Psychological sequelae and holistic approaches to intervention

Sophie Perry

North Wales Clinical Psychology Programme, Bangor University

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It was an absolute privilege to meet each and every participant who kindly agreed to participate in my research. I was struck by the willingness and openness of everyone I met and I thank you for sharing, not just your time but each of your stories with me.

I would like to express my sincerest gratitude to the team at the North Wales Brain Injury Service who welcomed me from day one, and without whom I would not have been able to recruit the participants and complete this thesis. I look forward to calling you my colleagues.

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Contents

Acquired brain injury: Psychological sequelae and holistic approaches to intervention

Abstract

This thesis aims to explore the role which psychological and neuropsychological processes play in the sequelae of acquired brain injury (ABI), and holistic intervention possibilities.

The first chapter consists of a systematic literature review and meta-analysis, examining the efficacy of using a physical exercise intervention to reduce reported symptoms of depression for people with an ABI. In total, 10 studies met the inclusion criteria and consisted of randomised controlled trials, non-randomised controlled trials and uncontrolled trials. In line with research in non-ABI populations, the current meta-analysis found a small to medium main effect of physical exercise on reducing reported symptoms of depression in people with an ABI. Data was not available to fully investigate the maintenance of this effect over time.

The second chapter examines the empirical research investigating the relationship of self-awareness with executive function and depression in people with an ABI. 25 prospectively recruited participants with confirmed ABI more than 12 months prior to the beginning of the study completed questionnaires and neuropsychological tests, pertaining to self-awareness, depression and elements of executive function. Hierarchical multiple regression revealed that depression and set shifting were significant predictors of level of self-awareness following ABI. This suggests that both psychological and specific neuropsychological factors (set shifting) contribute to impaired self-awareness following ABI. The clinical implications and the limitations of both research papers are discussed.

The third chapter discusses the papers referred to above in regard to theories of self-efficacy, which provides a potential psychological explanation as to why exercise appears to have a small to medium anti-depressant effect. It also explores how altered levels of self-awareness could influence the efficacy and delivery of physical exercise interventions. A reflective commentary is provided at the close of the thesis.

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The effectiveness of physical exercise as an intervention to reduce depressive symptoms following acquired brain injury: A meta-analysis and systematic review.

Sophie Perry[1] & Rudi Coetzer[2,3]

1. North Wales Clinical Psychology Programme, School of Psychology, Bangor University

2. North Wales Brain Injury Service, Betsi Cadwaladr University Health Board NHS Wales

3. School of Psychology, Bangor University

Address for correspondence: Sophie Perry, North Wales Clinical Psychology Programme, School of Psychology, Brigantia Building, Bangor University, Bangor, Gwynedd, LL57 2DG
Email – psp4f1@bangor.ac.uk Tel - 01248 388365 Fax: 01248 383718

This paper will be submitted to *Neuropsychological Rehabilitation* and as such will follow the submission guidelines for the journal.

The effectiveness of physical exercise as an intervention to reduce depressive symptoms following acquired brain injury: A meta-analysis and systematic review.

Alongside the obvious health benefits, physical exercise has been shown to have a modest anti-depressant effect for people in the general population. To the author's knowledge, there are no current literature reviews or meta-analyses available exploring this effect for people with an acquired brain injury (ABI). A systematic review of intervention studies utilizing physical exercise and mood outcome measures for an ABI population was performed in November 2016. Baseline and outcome data were extracted for the ten studies which met the inclusion criteria. Effect sizes were calculated for the four controlled trials and six uncontrolled trials and entered into the meta-analysis. Consistent with research in non-brain injury populations, the current meta-analysis identified a small to medium effect size of physical exercise on reducing depressive symptoms in people with an ABI. This would support further rigorous trials to provide additional evidence for the efficacy of physical exercise interventions for people with ABI. Limitations of the current meta-analysis and clinical implications are discussed.

Keywords: brain injury, depression, exercise, intervention, rehabilitation

Introduction

Acquired Brain Injury (ABI) is defined as an injury to the brain after birth but excludes neurodegenerative disorders (Headway, 2015). ABI can include Traumatic Brain Injury (TBI), which is an injury to the brain as a result of external force as well as acquired injuries such as the result of cardiovascular accident (CVA), tumour, haemorrhage, infection and more (Headway, 2015; Menon, Schwab, Wright & Maas, 2010). According to a report compiled by Headway (2015), there were 566 admissions per 100,000 people in the United Kingdom for ABI in 2013-2014. This represents an increase of 10% since 2005-2006. Figures were obtained using records of hospital admissions across the UK according to the International Classification of Disease Version 10 (ICD-10; World Health Organisation, 1992) diagnostic codes. ABI is associated with short and longer term disability, which is often a complex interaction between cognitive, physical and psychosocial impairment (Driver, Ede, Dodd, Stevens & Warren, 2012).

Depression and ABI

Depression is reportedly the most common psychiatric disorder to emerge following ABI (Koponen et al., 2002; Alderfer, Arciniegas & Silver, 2005; Bryant et al., 2010) with rates ranging between 10% and 77% (Varney, Martzke & Roberts, 1987; O'Donnell, Creamer, Pattison & Atkin, 2004). The variability in reported prevalence rates is likely to be due to the variability in the criteria used to identify the presence of depressive symptoms. Kreutzer, Steel & Gourley (2001) attempted to combat the significant variability by examining 722 outpatients with brain injury utilizing the DSM-IV criteria for depression. They found that 42% of outpatients met the criteria for a Major Depressive Disorder (DSM-IV; American Psychiatric Association, 2001).

Despite heterogeneity in reported rates of depression following ABI, it is clear that depressive symptoms are elevated a year following injury (Jorge, et al., 1993) and appear to remain elevated for up to a decade later (Holsinger et al., 2002). The development of depression following ABI is likely to be due to a combination of factors including neuro-biological changes, psychological adjustment and the social context in which the individual resides (Alderfer, Arcinniegas & Silver, 2005).

Depression following ABI can hinder the recovery process (Rosenthal, Christensen & Ross, 1998; Seel & Kreutzer, 2003; Mooney, Speed & Sheppard, 2005). Studies have shown that patients with depression following ABI have a lower quality of life, poorer health status and poorer psychosocial functioning than non-depressed individuals with ABI (Hibbard et al., 2004; Rapoport, Kiss, & Feinstein, 2006; Chamelian & Feinstein, 2006). Depressive symptoms have also been associated with worse global outcomes (measured by the Glasgow Outcome Scale) five to seven years following ABI (Whitnall et al., 2006).

Treatment of Depression Following ABI

There is evidence that depression following ABI responds well to antidepressant medication (see Fann, Hart & Schomer, 2009 for a systematic review). Selective Serotonin Reuptake Inhibitors are often recommended as a first line medication for depression following ABI due to their favourable profile of side-effects (see Warden et al., 2006). There appears to be some limited data available supporting the use of Electro Convulsive Therapy to reduce depressive symptoms following ABI but sample sizes are small and narrowly selected (Fann, Hart & Schoner, 2009).

Two controlled studies utilizing Cognitive Behavioural Therapy (CBT) with ABI populations reported an improvement in depressive symptoms. One study included 11

sessions of CBT (either telephone based or group format) with an education based intervention control group. CBT was modified for the ABI population including telephone reminders for homework amongst others. The CBT group reported an improvement in symptoms of anxiety and depression with a very large effect size (Cohen's $d = 1.79$) but there was no significant improvement for the education group. Interestingly there was no statistically significant difference in the improvement of symptoms between telephone or group CBT intervention (Bradbury et al., 2008). The other study utilized three sessions per week of modified CBT and cognitive rehabilitation for 11 weeks (n=20) for patients with ABI with reported emotional and cognitive complaints. The study had a wait list control design. The CBT group reportedly showed greater improvements in emotional functioning compared to the wait list control group (Tiersky et al., 2005). It should be noted that neither of the studies above had major depression as an inclusion criterion so it does limit the generalizability of the findings to ABI populations with major depression.

Qualitative research has explored the treatment preferences for people with depression following ABI using telephone interviews with depressed and non-depressed individuals 12 months following ABI (Fann et al., 2009). 84% of the sample (n=145) rated physical exercise as their preferred treatment method above all others (including talking therapy, antidepressant medication, group therapy, self-help and alternative medicine). Physical exercise intervention is often delivered in a group format and so would additionally prove to be a cost effective intervention (National Collaborating Centre for Mental Health UK, 2010).

Exercise intervention for depression in non-ABI participants

There are a number of reasons why it is plausible that exercise would have an anti depressant effect. It has been proposed that exercise can act as a distraction from negative thoughts (Nolen-Hoeksema & Morrow, 1993) but also can result in positive feedback from

others and an increase in self-esteem (Bosscher, 1993). Research has also suggested that physical exercise can lead to experiences of mastery which has been shown to be the most reliable way to increase self-efficacy and subsequently improve depression (Bandura, 1997; Craft, 2005; Peterson & Seligman, 1984). Animal studies have also demonstrated that exercise results in increased serotonogic drive (Gomez-Merino, Bequet, Berthelot, Chennaoui & Guezennec, 2001) and increased neurogenesis (Bjornebekk, Mathe & Brene, 2005) which can have an anti-depressant effect.

There are six systematic reviews and meta-analyses reviewing the use of exercise to reduce depressive symptoms in non-ABI populations available to the current author (Lawler & Hopker, 2001; Sjosten & Kivela, 2006; Stathopoulou, Powers, Berry, Smits, & Otto, 2006; Mead et al., 2009; Rethorst, Wipfli & Landers, 2009; Krogh, Nordentoft, Sterne & Lawlor, 2010). Conclusions from these reviews vary from reporting methodological weakness from trials and therefore no conclusive effect (Lawler & Hopker, 2001; Sjosten & Kivela, 2006) to the Cochrane review reporting a non significant moderate effect of exercise for reducing depressive symptoms when their analysis was limited to robust trials (Mead et al., 2008). Krogh and colleagues (2011) only included participants with a clinical diagnosis of depression whereas the other five reviews had much broader inclusion criteria. Krogh and colleagues (2011) concluded that exercise was shown to have a small effect on reducing depressive symptoms based on a standardized mean change of -.04, but follow-up data from five of the 13 studies suggested that this effect was no longer present after the intervention had finished.

To the author's knowledge, at the time of writing there were no systematic literature reviews or meta-analyses reviewing the use of exercise as an intervention to treat depression

following ABI. The present meta-analysis aims to answer the following question: *Is physical exercise an effective intervention to reduce depressive symptoms following ABI?*

Method

Identification and selection of studies

Three electronic databases (PubMed, PsychInfo and Web of Science) were searched in November 2016. The following Boolean search terms were used: "brain injur*" AND "exercise" AND ("mood" OR "depress*"). An ancestral search of identified published articles was also conducted. The search was limited to articles published in English. Initially, articles were screened via examination of abstracts and then full articles were assessed according to the following inclusion criteria:

- Participants must be aged 18 or older and have sustained an ABI. Including TBI and CVA.
- Interventions must utilize physical exercise.
- Research papers must be clinical trials.
- Study data must be quantitative.
- Studies must have a depression related outcome measure.
- Control group data must be from a comparable population, if not the study will be analyzed as a non-controlled trial.

Where data was missing in the published papers, authors were contacted by email and via Research Gate (three reminders were sent to non-responders).

Assessment of study quality

Study quality or methodological rigour of each study included in the analysis was assessed utilizing the criteria proposed by Reichow, Volkmar and Cicchetti (2008). This method was selected as it has been shown to have sound psychometric properties (Reichow et al., 2008) and is deemed to be superior to alternative methods (Wendt & Miller, 2012). Each study in the current meta-analysis was evaluated according to Reichow's (2011) primary and secondary indicators for research design. Each indicator (for example, participant characteristics, independent variable etc.) was rated as high, acceptable or unacceptable. Based on the number of ratings for each indicator, a strength rating can be determined by Reichow and colleagues' (2008) original classification. This results in a rating of strong, adequate or weak methodological rigour. See Table 1 for individual ratings of studies included in the meta-analysis.

Data analysis

Data for standardized measures related to mood or depression were extracted from each paper by the principal author, where multiple measures were available, only those relating to depression were extracted. All statistical analyses were conducted via the Metafor package (Viechtbauer, 2010) for the statistical software environment, R (Team, R., 2016). The effect sizes for each study were calculated using the mean change in scores divided by the baseline standard deviation (Jansen, Viechtbauerm Lenssen, Hendriks & A de Bie, 2011). For controlled trials, the difference between effect sizes for the two arms of the trial were used, for uncontrolled trials, the effect size from baseline to post intervention was calculated relative to zero (Viechtbauer, 2010). Positive values represent an average improvement in scores from baseline to post-intervention measures. An effect size of 0.2 can be interpreted as a small effect, 0.5 as a medium effect and 0.8 as a large effect. To estimate the standard error of the calculated effect sizes, the pre and post-test correlations were extracted from the

literature for each of the standardized measures included in the meta-analysis (Aben, Verhey, Lousberg, Lodder & Honig, 2002; Beck, Steer & Brown, 1996; Curran, Andrykowski & Studts, 1995; Radloff, 1977).

A meta-analysis to establish the average effect of exercise intervention across the selected studies was conducted. There are two largely accepted models used to compute a meta-analysis, a fixed effect model and a random effects model (Hunter & Schmidt, 2000). A fixed effect model works on the assumption that the true effect within each study is essentially the same and that any difference in observed effect size represents random error. A random effects model allows the meta-analysis to predict an overall Standardised Mean Change (SMC) based on the distribution of true effect sizes. This distribution represents random error as in the fixed effects model but also true difference in effect size due to variance between studies (Borenstein, Hedges & Rothstein, 2007). It was hypothesized that there would be systematic differences between the studies (heterogeneity) due to variation within the interventions used and anticipated variability in methodological rigour. A random effects model was therefore the most appropriate method for the present meta-analysis. The random effects meta-analysis was run using Metafor for R (Viechtbauer, 2010) and calculated the SMC which represents the average of a distribution of values.

Results

Of the 204 articles screened via examination of abstracts, 136 were deemed not to be relevant to the topic of interest and were excluded. This left 68 articles to be assessed in full according to the inclusion criteria described above. Of the 68 full-text articles assessed, 11 were identified as satisfactorily meeting the inclusion criteria above, however unfortunately one author did not respond to requests for data; therefore 10 final studies were included in the

meta-analysis. Figure 1 illustrates the flow of studies through the meta-analysis. The designs of the final studies included randomized control trials, non-randomized control trials and non-controlled trials.

Characteristics of studies included

Quality: The methodological quality of the studies included in the analysis were all rated to be of 'Adequate' (Chin, Keyser, Dsurney & Chan, 2015; Damiano, Zampieri, Acevedo & Dsurney, 2016; Driver & Ede, 2009; Lee, Ashman, Shang, & Suzuki, 2014; Schwandt et al., 2012; Weinstein et al., 2016; Wise, Hoffman, Powell, Bombadier & Bell, 2012) or 'Strong' quality (Bellon et al., 2015; Bateman et al., 2001; Rzezak et al., 2015).

Participants: All participants were recruited from the community, were over the age of 18 and provided informed consent to participate in the individual studies. Eight out of the 10 studies relied on a diagnosis of a TBI or an ABI from a physician, whereas two of the studies relied on self reported TBI (Bellon et al., 2015 & Wise et al., 2012). All participants had experienced a brain injury at least six months previous to participating in the study. Severity of TBI was only reported in three of the 10 studies and was reported as mild-moderate (Chin et al., 2015 & Rzezak et al., 2015) and moderate-severe (Schwandt et al., 2012). Two studies had healthy volunteer control groups which were not included in the analysis and were treated as uncontrolled trials (Damiano et al., 2016 & Rzezak et al., 2015). One study used a wait list control group (Lee et al., 2014) and three had control groups participating in alternative interventions including nutrition education (Bellon et al., 2015), relaxation training (Bateman et al., 2001) and vocational rehabilitation training (Driver & Ede, 2009). All of the control groups included in the analysis were from a brain injury population with three studies randomizing participants to either group (Bateman et al., 2001; Bellon et al., 2015; Driver & Ede, 2009).

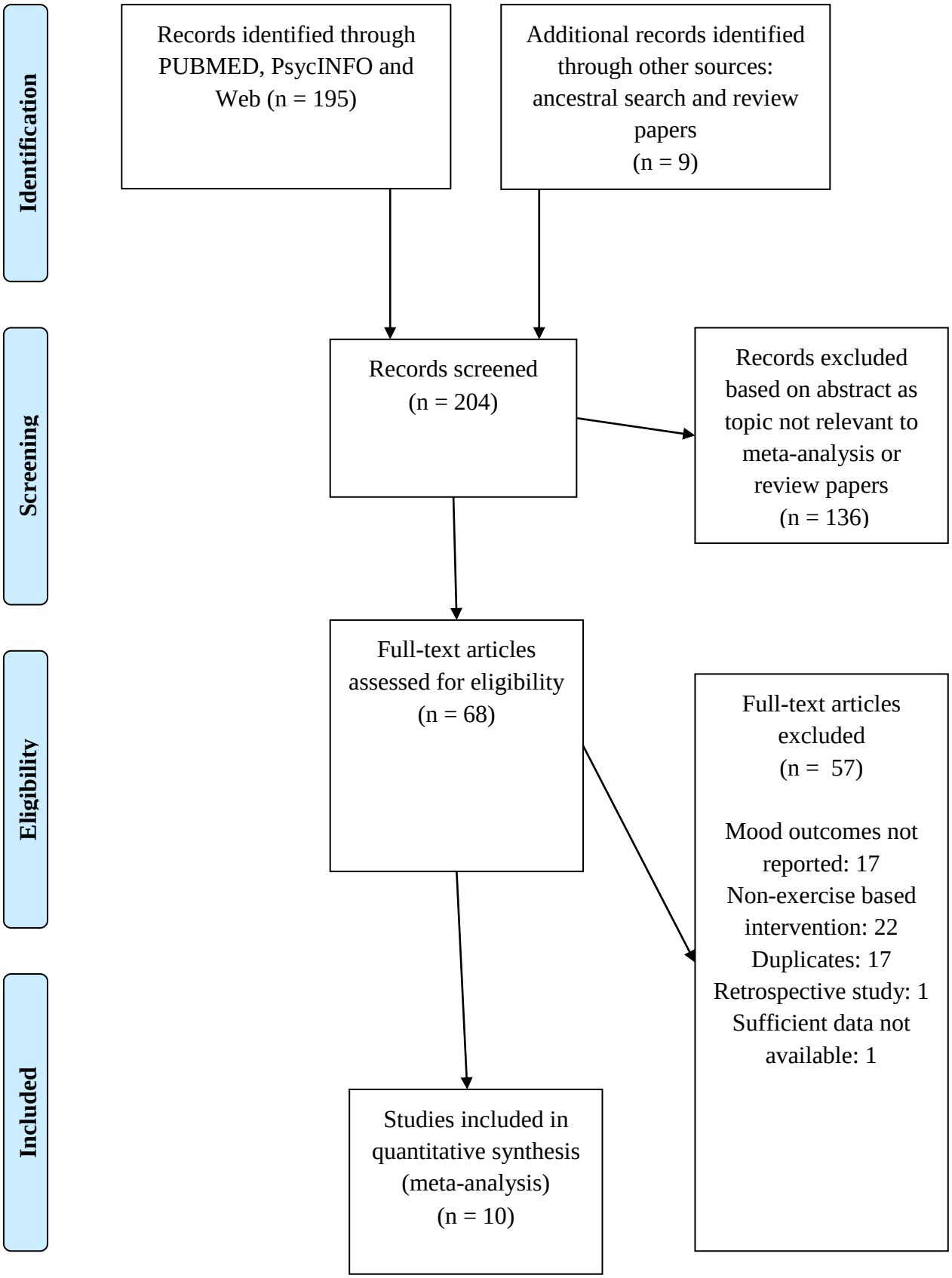

Figure 1. Flow diagram showing study selection process (PRISMA, 2009)

Intervention type: Nine out of the 10 studies had an aerobic intervention including treadmill, exercise bike and swimming, one study used a walking intervention. The intervention length was between eight and 12 weeks apart from one study which had just two sessions, one week apart (Rzezak et al., 2015). All interventions had a supervised element with home practice being set in between supervised sessions.

Outcome measures: All of the studies in the meta-analysis used a mood related outcome measure including the Beck Depression Inventory (BDI-II; Beck, Steer & Brown, 1996), The Hamilton Depression Inventory (HAM-D; Hamilton, 1960), The Profile of Mood States – Short Form (POMS-SF; Curran, Andrykowski & Studts, 1995), The Brunel Mood Scale (BRUMS; Terry & Lane, 2003), Centre for Epidemiological Studies-Depression Scale (CES-D; Radloff, 1977) and the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983). See Table 1 for a summary of studies included in the meta-analysis.

Table 1. Summary of included studies (n=10)

Author/Year	Design	N (pre)	N (post)	Control group	Mean Age (SD)	Time since injury	Sex M:F	Outcome Measure	Summary of Intervention	Findings	Setting	Quality rating (Reichow et al., 2008)
Damiano et al. (2016)	Non-Controlled Trial	24	24	Healthy Volunteers not included in analysis	31.3 (9.4)	TBI >6 Months	14:10	HAM-D	Elliptical training at home over 8 weeks, 5 days per week at 30 minutes per session	Improvement in sleep and scores on the HAM-D compared to non-TBI control	Community	A
Weinstein et al. (2016)	Non-Controlled Trial	10	10	No	32.9 (6.5)	TBI >6 Months	4:6	POMS-SF	Aerobic treadmill exercise supervised, 12 weeks, 3 per week, 30 minute sessions, heart rate maintained at 70-80% of reserve.	Improvement in long and short-term mood responses	Community	A
Bellon et al. (2015)	Randomized Control Trial	69	69	Yes Nutrition education program	43.7 (15.8)	TBI >6 Months	41:28	CES-D	Home-based walking program measure via pedometer aim 5% increase per week until goal of 40% increase in weeks 8-12. Coaching contact 3 times per week tapered off at end	Improvement in depression symptoms following the program	Home-based	S
Chin et al. (2015)	Non-Controlled trial	7	7	No	33.3 (7.9)	TBI >6 Months	2:5	BDI-II	Aerobic treadmill exercise supervised, 12 weeks, 3 per week, 30 minute sessions, heart rate maintained at 70-80% of reserve.	Improvement in cardiovascular fitness no changes in BDI-II	Medical Research Center	A
Rzezak et al. (2015)	Non-Controlled Trial	24	24	Yes Healthy Volunteers not included in analysis	31.83 (9.5)	TBI >6 Months	24:0	BRUMS	2 sessions between 1-2 weeks apart. 1st session cycling at high intensity until voluntary exhaustion. 2nd session 30 minutes cycling of moderate intensity exercise.	Reductions in depression and anxiety symptoms compared to controls	Laboratory	S

Lee et al (2014)	Non-Randomized Control Trial	21	21	Yes Waiting list control group	46.1(15.2)	TBI >12 Months	9:12	BDI-II	Group exercise instructor led 60 minutes twice per week for 8 weeks. Physical exercises accompanied by verbal affirmations (IntenSati)	Less depressive symptoms and more positive affect after completion of the program	Rehabilitation Outpatient Department	A
Schwandt et al. (2012)	Non-Controlled Trial	4	4	No	29 Range 19-48	TBI<6 Months	3:1	HAMD	Supervised aerobic either cycle, treadmill or step machine 3 times per week over 12 weeks. 30 minutes exercise plus warm up and cool down	Reduction in depressive symptoms and increase in self-esteem	Hospital	A
Wise et al. (2012)	Non-Controlled Trial	40	40	No	39.7 (12.6)	TBI >6 Months	15:25	BDI-II	Supervised once per week 30mins aerobic exercise and education with further 4X 30 min sessions unsupervised. Telephone follow-up	Exercise was maintained and depressive symptoms reduced	Community	A
Driver & Ede (2009)	Randomized Control Trial	16	16	Yes Vocational Rehabilitation Class	37.65 (2.34)	TBI >12 Months	Missing data	POMS	8 Week aquatic exercise class (24 sessions, aerobic and resistance) 1hour per session. Control was 8 week reading and writing skills class	Increase in positive mood in aquatic group reduction in negative – anxiety and depression.	Community	A
Bateman et al. (2001)	Randomized Control Trial	49	49	Yes Relaxation training	43.2 (13.8)	ABI >6 Months	97:60	HADS	Individual supervised 3 half hour sessions per week over 12 weeks of relaxation or aerobic cycle training	Both groups showed non-significant improvement on the HADS	Hospital	S

Effect of exercise intervention

See Figure 2 for a forest plot illustrating the meta-analysis of all 10 studies with the main outcome measure following the completion of the exercise intervention. The pooled SMC was 0.41 (95% CI 0.08 to 0.75). This represents a statistically significant positive small to medium overall effect size of physical exercise to reduce depressive symptoms in people following ABI. Tests of heterogeneity were significant (p<0.01), confirming that heterogeneity was present amongst the studies included in the analysis. A funnel plot of the studies included in the meta-analysis (see Figure 3) revealed a couple of smaller studies with large effect sizes (Driver & Ede, 2009; Schwandt et al., 2012), it is possible that this

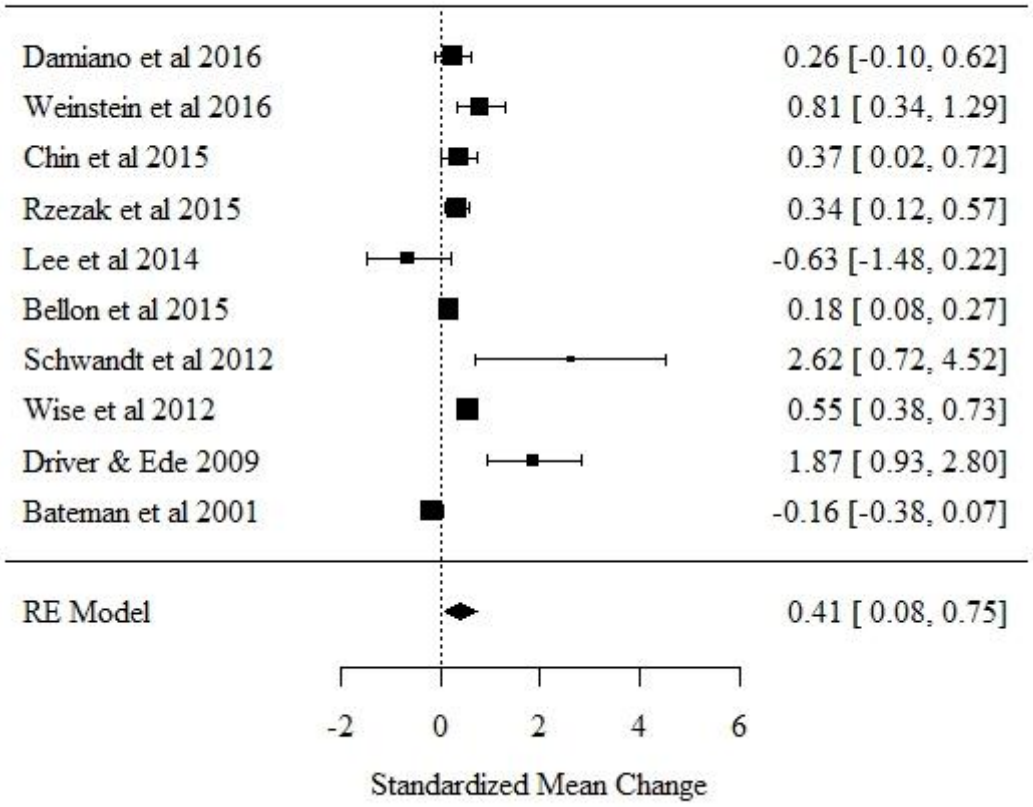

Figure 2. Meta-analysis of exercise intervention studies using exercise intervention to reduce depressive symptoms in people following ABI.

represents a slight positive publication bias in the literature and a wider distribution of effect sizes amongst smaller studies would be expected. It is unlikely that small studies with small or non-significant results are published, thus it is common to find publication bias in the

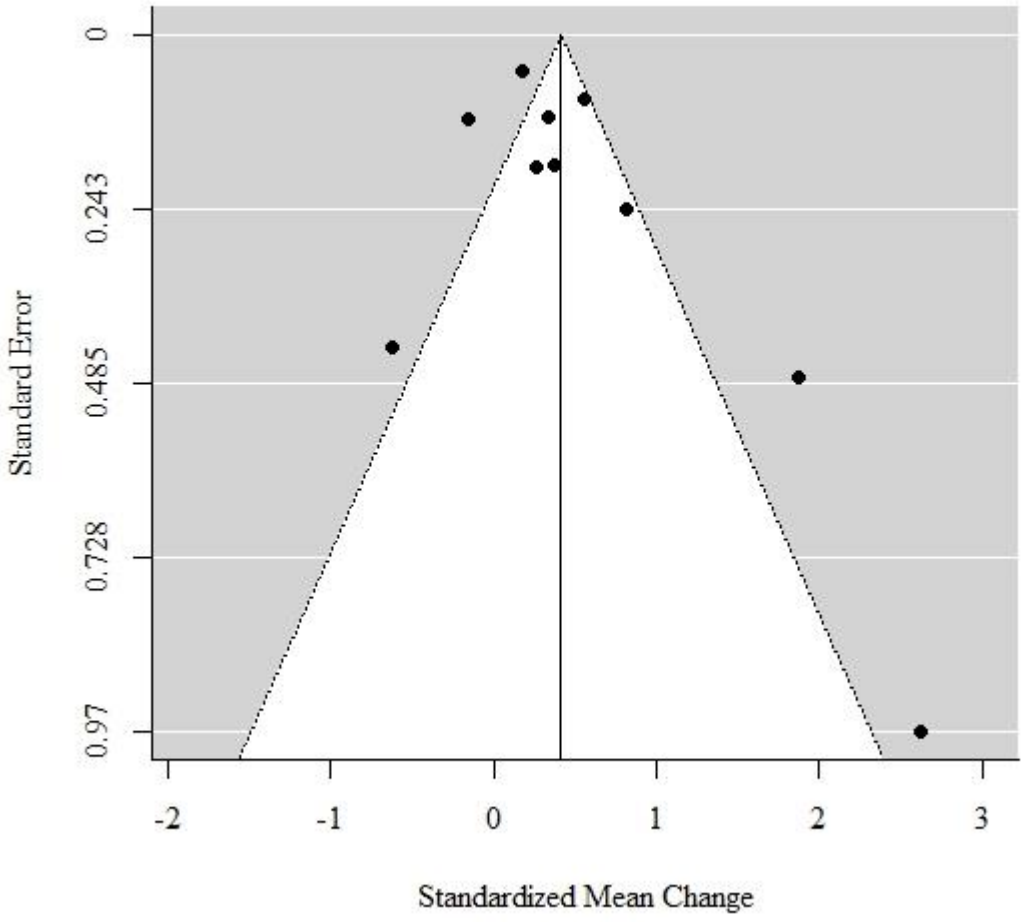

Figure 3. Funnel plot of all studies included in the meta-analysis

literature. As a conservative method to assess whether or not the smaller studies were unduly skewing the results of the meta-analysis, the analysis was re-run excluding the two smaller studies. The results showed an overall SMC of 0.27 (95% CI 0.05 to 0.49) which falls within the statistically significant small to medium effect size range, suggesting that there is a small

but positive effect of exercise in reducing depressive symptoms in people with an ABI, despite heterogeneity between the studies used in the analysis.

As a conservative assessment of difference between the controlled and uncontrolled studies; the analysis was also re-run including only the controlled trials and only the uncontrolled trials separately. The overall SMC was 0.27 (95% CI -0.69 to 1.24) when only the controlled trials were included in the analysis. The overall SMC when the analysis was re-run for only the uncontrolled trials was 0.46 (CI 0.32 to 0.61). Heterogeneity remained evident between studies for both of the analyses above.

Discussion

The small to medium main effect of exercise on reducing depressive symptoms in the current meta-analysis appears comparable to previous meta-analyses investigating the effectiveness of exercise on depression in non-ABI populations (Krogh, Nordentoft, Sterne & Lawlor, 2011; Mead et al., 2008).

The current meta-analysis supports the use of exercise to reduce depressive symptoms whilst the individual is engaged in the exercise intervention, but only one study included in the meta-analysis provided six month follow up data to assess change over time (Wise et al., 2012). Scores on the BDI reduced on average by five points (scores range from zero – 63 with scores above 29 indicating clinically significant levels of depression), from baseline to 10 week measures, there was no further reduction in BDI scores at six month follow up but the reduced scores were maintained and participants reported continuing to exercise for an average of 146.6 minutes. Unfortunately the authors did not collect data from the control

group at six month follow-up. It will be important for future exercise intervention studies to collect follow-up data for intervention and control groups to further understand the effect of change over time. Initial results from Wise and colleagues (2012) are however promising.

Study Quality

It was not possible to conduct a meta-analysis solely including randomised controlled trials due to the relative lack of published research which met the inclusion criteria described above. Only three randomized controlled trials were available in the literature (Bateman et al., 2001; Bellon et al., 2015; Driver & Ede, 2009). Driver and Ede (2009) randomly allocated participants who met the inclusion criteria to either a vocational rehabilitation control group or the physical exercise group, but assessors were not blinded to the randomization. Similarly Bellon et al. (2015) randomly allocated participants to control (nutrition education) or a walking (exercise) group but the arms of the study were not blinded.

Bateman and colleagues (2001) utilized full prospective randomized control trial methodology including blinding the assessors to all conditions and they had no involvement in the intervention. Interestingly there was a large discrepancy in the effects sizes between the RCTs. Driver and Ede (2009) finding an effect size for exercise on depressive symptoms as compared to a control group of 1.87, meaning that the participants in the exercise group were averagely scoring 1.87 standard deviations lower (representing an improvement) on depression related measures relative to the control participants. Bellon et al. (2015) found a more modest improvement in depression related outcome measures for the exercise group compared to the control group (0.18) and Bateman et al. (2001) found a slight negative effect of exercise on depressive symptoms (-0.16) compared to the change in scores for the control

participants. It would be reasonable to assume that Bateman et al. (2001) were reporting an effect size closer to the 'true' effect due to a large sample size (n=49) and more stringent randomized methodology. Although the authors reported a non-significant trend towards improvement on the HADS questionnaire, the effect size calculates the change in scores relative to the control group who completed a relaxation programme. It would therefore appear that in Bateman et al.'s (2001) study, the control group reported marginally more improvement on the HADS than the exercise group.

The RCTs differed in the delivery of the intervention, whereby Driver and Ede (2009) delivered a group aquatic programme and Bateman et al. (2001) and Bellon et al. (2015) delivered one to one training. To understand whether group delivered exercise intervention is more efficacious, vastly more research is needed using methodologically sound RCTs to be able to utilize a meta-regression, to explore the potential differences in efficacy due to intervention delivery method. It should also be noted that the three control groups undertook different interventions which included a relaxation group (Bateman et al., 2001), a vocational rehabilitation group (Driver & Ede, 2009) and a nutrition educational programme (Bellon et al., 2015). Therefore the SMC was ultimately representing differences in change between exercise interventions and differing control conditions, which will likely differ in their own effect on depression measure scores.

One non-randomized controlled trial (Lee et al., 2014) was included in the analysis. The study utilized a waiting list control group design whereby participants were allocated to either group dependent on their personal circumstances and availability. Potentially this could indicate that participants who were available for the intervention group were more motivated

to participate in an exercise intervention, thus it is important to consider the effect of non-randomization when interpreting the results.

The remaining six studies included in the analysis were non-controlled trials (Chin et al., 2015; Schwandt et al., 2012; Weinstein et al., 2016; Wise et al., 2012) or were controlled trials with healthy volunteer data which was not included in the analysis (Damiano et al., 2016; Rzezak et al., 2015). Due to the lack of controlled trials utilizing an exercise intervention to reduce depressive symptoms following ABI, it was important to include the uncontrolled trials in the meta-analysis. This does however highlight important issues with the analysis. The effect sizes for the controlled trials were calculated relative to the change in the control group whereby the uncontrolled trials were calculated relative to zero. As expected, the overall SMC for the uncontrolled trials was larger than that for the controlled trials but both still fell within the small to medium effect size range.

Limitations

There were several limitations to the current meta-analysis. Due to the small number of controlled intervention studies, the analysis included uncontrolled trials and controlled trials which likely contributed to the heterogeneity between studies in the analysis. Also due to the small number of studies that met the inclusion criteria, it was not possible to run further regression analyses to understand the effects of different specific exercise interventions, group versus one to one, duration of intervention etc. It will be important to investigate these potential predictive variables when more research becomes available in the literature.

As with all meta-analyses, there is the risk of inflated type I publication bias towards research published with significant positive findings. As discussed above, this is likely the

case for the current meta-analysis but when controlling for this using the conservative method of re-running the meta-analysis, there remained a small but positive overall effect of exercise on reducing depressive symptoms.

Conclusion

In conclusion, exercise may be efficacious in reducing depressive symptoms in individuals who have sustained an ABI. It would support the use of exercise referral schemes for people with neurological impairment, in line with the National Institute for Health and Clinical Excellence guidance (NICE, 2014). The heterogeneous sample of studies available to the current meta-analysis has made it difficult to draw comprehensive conclusions. It will be imperative for future research to include properly controlled trials to further understand the effect of physical exercise on reducing depressive symptoms in people who have sustained an ABI. The potential cost effectiveness of group exercise programmes (National Collaborating Centre for Mental Health UK, 2010) and feedback from patients' preferences (Fann et al., 2009) would support further research into the area.

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Chapter 2 – Empirical Research Paper

Instructions for contributors

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The *Journal of the International Neuropsychological Society* is the official journal of the International Neuropsychological Society, an organization of over 4,500 international members from a variety of disciplines. The*Journal of the International Neuropsychological Society* welcomes original, creative, high quality research papers covering all areas of neuropsychology. The focus of articles may be primarily experimental, applied, or clinical. Contributions will broadly reflect the interest of all areas of neuropsychology, including but not limited to: development of cognitive processes, brain-behavior relationships, adult and pediatric neuropsychology, neurobehavioral syndromes (such as aphasia or apraxia), and the interfaces of neuropsychology with related areas such as behavioral neurology, neuropsychiatry, genetics, and cognitive neuroscience. Papers that utilize behavioral, neuroimaging, and electrophysiological measures are appropriate.

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Self-awareness following acquired brain injury is linked with depression and higher order cognitive function.

Sophie Perry[1] & Rudi Coetzer[2,3]

1. North Wales Clinical Psychology Programme, School of Psychology, Bangor University

2. North Wales Brain Injury Service, Betsi Cadwaladr University Health Board NHS Wales

3. School of Psychology, Bangor University

Address for correspondence: Sophie Perry, North Wales Clinical Psychology Programme, School of Psychology, Brigantia Building, Bangor University, Bangor, Gwynedd, LL57 2DG
Email – psp4f1@bangor.ac.uk Tel - 01248 388365 Fax: 01248 383718

This paper will be submitted to *Journal of the International Neuropsychological Society* and as such will follow the submission guidelines for that journal.

Self-awareness following acquired brain injury is linked with depression and higher order cognitive function.

ABSTRACT

Objective. The current study aimed to examine the potential relationship between self-awareness, executive function and depression in post-acute acquired brain injury.

Method. 25 participants prospectively recruited from a community brain injury rehabilitation service completed the Awareness Questionnaire (AQ), the Hospital Anxiety and Depression Scale (HADS), the Trail Making Task (TMT) and the Wisconsin Card Sorting Test (WCST). Each participant's treating clinician also completed the Awareness Questionnaire (clinician form) for comparison.

Results. Hierarchical multiple regression revealed that depression (HADS) and set shifting (TMT) were significant predictors of level of self-awareness (AQ) following acquired brain injury. Contrary to previous research, the Wisconsin Card Sorting Test was not predictive of self-awareness.

Conclusion. Consistent with previous research, reduced self-awareness appears to be protective against symptoms of depression even after the acute stages of recovery. Clinical implications include the importance of monitoring levels of self-awareness even in post-acute ABI, including neuropsychological and psychological factors that might be contributing to and maintaining varying levels of self-awareness.

Keywords: Acquired Brain Injury, Awareness, Depression, Executive Function, Post-Acute, Neuropsychological Rehabilitation.

INTRODUCTION

Acquired brain injury (ABI) is an umbrella term that refers to an injury to the brain following birth but excludes neurodegenerative disorders such as the dementias and multiple sclerosis. Self-awareness in this context refers to the ability of an individual with an ABI to recognise difficulties acquired as a result of the injury (Crosson et al., 1989). Deficits in self-awareness are common following ABI (Schacter, 1990; Sherer, Hart & Nick, 2003) and reportedly cause the most impact on quality of life as reported by caregivers (Ergh, Rapport, Coleman & Hanks, 2002).

Deficits in self-awareness are important to identify as they can seriously hamper rehabilitation efforts. It is logical that without adequate awareness of deficits following ABI, the patient will not be motivated to engage in rehabilitation and to learn techniques to compensate for such deficits (Allen & Ruff, 1990; Askenasy & Rahmani, 1987; Prigantio, 1988; Groswasser, Mendelson, Stem, Schechter & Najenson, 1977; Najenson et al., 1975; Schachter, Gilsky & McGlynn, 1990). Researchers have found that patients with ABI and reduced self-awareness will consistently demonstrate greater impairment in self-awareness for cognitive and behavioural difficulties as opposed to physical difficulties (Hendryx, 1989; Prigantio, Altman & O'Brien, 1990).

Self-awareness and depression

Psychologically based theories of self-awareness suggest that reduced self-awareness following ABI is influenced by pre-morbid personality and is the result of a 'psychological defence mechanism' (Gainotti, 1993; Prigatano, 1996; Weinstein & Kahn, 1955) which acts as a protective barrier against depression. Research has demonstrated a negative relationship

between self-awareness and depression (Malec, Machulda & Moessner, 1997; Wallace & Bogner, 2000) whereby people with reduced self-awareness are more protected from depression compared to those who have intact awareness of their difficulties. Malec, Testa, Rush, Brown & Moessner (2007) examined the relationship between depression following ABI, self-awareness and demographic data. They found a strong association between self-awareness and depression whereby those participants with impaired self-awareness reported less depressive symptoms. Malec et al. (2007) interpreted this association as reduced self-awareness providing a barrier to depression, which would be consistent with psychologically based theories of self-awareness (Gainotti, 1993; Prigatano, 1996; Weinstein & Kahn, 1955). Furthermore, this effect was consistent amongst orthopaedic participants who had not sustained a brain injury. One major limitation of the above study is that the self-awareness measure was developed post-hoc from self reported measures of impairment; therefore repetition with standardised measures would be needed.

In the social psychology literature, it has been suggested that reduced levels of self-awareness can in fact be related to increased levels of depression, contrary to the research described above. According to theories of self-efficacy (Bandura, 1977; Gage, & Polatajko, 1994) reduced self-awareness can result in outcomes or failures that were unexpected and can lead to feelings of insecurity for the individual. This environmental feedback has been linked to confusion, loss of control and depression which ultimately result in decreased self-efficacy (see Toglia & Kirk, 2000).

Self-awareness and executive function

'General disorder theories' suggest that deficits in executive function lead to reduced self-awareness (Mesulam, 1985; Shallice & Burgess, 1991; Stuss, 1991). Executive function

is an umbrella term used to describe the plethora of complex higher order cognitive abilities that allow humans to *"formulate goals; to initiate behaviours; to anticipate the consequences of action; to plan and organise behaviour according to spatial, temporal, topical or logical sequences; and to monitor and adapt behaviour to fit a particular task or context"* (Cicerone et al., 2000; p1605). Impairments in executive function following ABI are common. Ponsford and colleagues (2014) reported in their longitudinal study that 45% of their participants (n=41) experienced some difficulties with executive function 10 years post ABI.

A number of studies have investigated the relationship between various measures of executive function and self-awareness but findings appear to be inconclusive. Some studies have found significant relationships between measures indicating impaired self-awareness and elements of the Wisconsin Card Sorting Test (specifically number of categories completed and number of perseverative responses) indicating that decreased ability to inhibit a response and poor flexibility may play a part in decreased self-awareness (Bivona et al., 2008; Noe et al., 2005). Other studies failed to find any significant correlations between reduced self-awareness and measures of executive function (Bach & David, 2006; O'Keefe Dockree, Moloney, Carton & Robertson, 2007). It is possible that the inconsistencies in these studies could be explained by differences in methodological rigour and in the tools used to measure self-awareness and executive function. Additionally, the studies do not account for depression; therefore it is difficult to draw any firm conclusions.

The aim of the current study was to address some of the issues mentioned above by investigating whether there was a link between measures of self-awareness (with good reliability) and elements of executive function, but also what role depression plays in the relationship.

METHOD

Participants

Power analysis (parameters: ß=0.80, α = 0.05) indicated that to detect a medium sized correlation, the sample size required was 29. The final group of participants consisted of 25 prospectively recruited individuals with an ABI all aged between 25 and 69. The nature of ABI ranged from TBI (classified as moderate to severe), Cerebral Vascular Accident (CVA), encephalitis and tumour, with the time since injury ranging from 14 months to 43 years. All participants were receiving ongoing care from a community brain injury rehabilitation service commissioned by the National Health Service in the United Kingdom. Participants were referred to the service by health professionals for a range of physical, emotional or cognitive difficulties as a result of their ABI. Further demographic information is included in Table 1.

Table 1. Participant demographic data

	Entire sample (n=25)	TBI (n=18)	CVA (n=5)	Other (n=2, encephalitis and tumour)
Age M (SD)	49.8 (11.41)	48.67 (11.95)	55.2 (9.90)	46.5 (10.60)
Sex (Male : Female)	21:4	15:3	5:0	1:1
Time (months) since injury M (SD)	106.1 (116.30)	116.22 (134.39)	72.8 (48.50)	98.5 (30.40)
Education (years) M (SD)	13.2 (2.10)	12.94 (1.59)	13.2 (3.30)	16 (0)
Employment status (employed : unemployed)	6:19	5:13	0:5	1:1

Initially, ABI was confirmed either by examination of clinical imaging (e.g. Magnetic Resonance Imaging or Computerised Tomography) or confirmation from the consultant

neurologist as a routine process to determine appropriateness for the community brain injury rehabilitation service. Further information regarding the nature and site of the ABI were collected with consent from each participant by the principal author via retrospective examination of medical notes.

Exclusion criteria were utilised to control for confounding variables. Participants were excluded from the study if they sustained an ABI less than 12 months before the study, had any current substance misuse difficulties, any co-morbid neurodegenerative disease or a previous diagnosis of an intellectual disability.

Measures

Demographic data

The principal author collected demographic information from each participant, including: age, sex, work status, highest achieved education level, time since injury and nature and site of injury.

Measures of awareness

Self-awareness was measured using the Awareness Questionnaire (AQ; Sherer, Bergloff, Boake, High & Levin, 1998) which consists of three forms; patient, significant other and clinician. The questionnaires are designed to assess the amount of insight or self-awareness the participant has about their functioning following ABI. The patient form and significant other form consists of 17 items while the clinician form consists of 18. The extra item allows the clinician to rate their own perception of the patient's self-awareness. Each item on the forms addresses the patients' current abilities as compared to their abilities pre-

injury. Scores range from 17 to 85, the discrepancy between the clinician and patient rating is calculated, and a discrepancy >20 represents clinical levels of impaired self-awareness (Evans, Sherer, Nick, Nakase-Richardson & Yablon, 2005). The discrepancy scores range from -68 to 68 where negative scores represent an over-estimation of difficulties (Cicerone, 1991; Prigatano & Altman, 1990). Internal consistency for the scale is Cronbach's α of .88 for patient and significant other (Sherer et al., 1998). In a more recent study, Cronbach's α values of .84 (patient), .91 (clinician) and .89 (significant other) were found across the entire scale (Carroll & Coetzer, 2011). The current study will utilise the patient and clinician forms due to predicted difficulty in obtaining significant other ratings.

Measures of higher level cognitive function

The Wisconsin Card Sorting Test was used (WCST; Heaton et al., 1993) to measure various aspects of executive function including perseveration and flexibility. This task can be administered via a computerised version or by hand, the current study used the manual version. The participant is required to match cards (128) to their target cards (four) according to rules (colour, shape or number) which are unknown to the participant. Participants are to work it out via feedback from the examiner of 'correct' or 'incorrect'. The rules change throughout the test and the participant is required to independently shift to the new rule. The WCST is used widely to measure executive function and has been used in a number of populations (Romine & Reynolds, 2005). Generalisability coefficients are reported for the nine sub-scores within the WCST and range from 0.39 to 0.72 (mean = 0.57; Heaton et al., 1993). Generalisability coefficients of 0.60 and above are deemed to show very good reliability (Cicchetti & Sparrow, 1981; Mitchell, 1979). Due to the limited sample size, it was decided to concentrate on the number of categories completed (WCST categories) and

perseverative errors (WCST perseverative errors) as a measure of flexibility and inhibition in line with previous research (Bivona et al., 2008; Noe et al., 2005).

The Trail Making Task (TMT; Reitan, 1958) was also selected as a traditional test of set shifting. In part A, participants connect 25 numerical targets as quickly as possible. Targets are numbered from one to 25 and they are connected sequentially. In part B, participants are required to connect targets switching between numbers and letters, sequentially, e.g. 1-a, 2-b, 3-c etc. The time taken to complete each task is recorded and the difference between time taken to complete TMT A and B will be calculated. The TMT has been shown to have good reliability for part A (r = 0.75), part B (r = 0.85) and the difference between part A and B (r = 0.74; Giovagnoli et al., 1996). The current study will use the difference between TMT A&B as it has been shown to minimise the visuo-perceptual and working memory demands, resulting in a more specific measure of set shifting (Sanchez-Cubillo et al., 2009).

Measures of psychological affect

The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) was used as a measure of psychological affect. The HADS is a self-report questionnaire that consists of 14 items giving separate subscale measures of anxiety and depression, where higher sores represent higher levels of anxiety and depression. Subscale scores of 0 – 7 are considered to be in the 'normal range', 8 – 10 'borderline range', and 11-21 are considered to be in the 'abnormal' or 'clinical' range. The HADS is deemed to have sound psychometric properties with a Cronbach's α from 0.68 to 0.93 (mean α=0.83) for the anxiety subscale and 0.67 to 0.90 (mean α=0.82) for the depression subscale (Bjelland, Dahl, Haug & Neckelmann, 2002). It has also be shown to be a reliable measure to be used with ABI

populations as it has an emphasis on behavioural and affective symptoms and the exclusion of items pertaining to physical symptoms (Whelan-Goodinson, Ponsford & Schonberger, 2009).

Procedure

Full ethical approval was granted by the National Health Service Research Ethics Committee (NHS REC) and the School of Psychology at Bangor University, UK. Following approval, participants were approached in the first instance by their treating clinician at the brain injury rehabilitation service to register interest in the study, and gain verbal consent for the principal author to contact them via telephone at a later date. The principal author made contact with each potential participant to answer questions and to arrange a convenient time for testing if they wished to participate. Testing was completed in an NHS clinic room local to the participant or in their own home at their convenience or preference. Fully informed verbal and written consent was gained from each participant who agreed to take part. Testing was completed in a quiet environment free from distractions and took around one hour on average. All participants were fully debriefed following assessment and given the option of receiving their individual results at a later date.

Statistical Analysis

The statistical software package IBM SPSS version 24 (IBM Corp, 2016) was used to complete all statistical analyses. In the first instance independent sample *t*-tests were run to see if there were any significant differences in measures of self-awareness between the TBI and CVA participants. If no significant differences were found then it would be appropriate to run the analysis on the entire sample. It was not deemed appropriate to run the *t*-test for the 'other' category as only two participants fell into this category. A hierarchical multiple

regression was run to understand the individual contributions of the independent variables to the explanation of variance within the AQ. Due to the exploratory nature of the present study and the inconclusive findings from previous research, it is not possible to compare the current findings with an existing model. To ensure a thorough analysis of the current data, the regression model was run with the AQ discrepancy as the dependent variable and demographics (age and education) at the first step, as these are fundamental qualities of each participant. Due to the order of variables entered into regression models having an effect on the significance levels, it was prudent to compare the regression models with each combination of variables to ensure results were consistent. The proceeding regression analyses were run for the remaining variables in each possible order of entry (six ways) with the WCST measures consistently grouped together. The best fitting regression model was the model in which each variable continued to improve the fit, yet remained parsimonious.

RESULTS

There was no significant difference between TBI and CVA participants on the dependent variable ($t_{(21)} = .078$, $p = .233$), therefore the participants were pooled into one sample.

The discrepancy analysis between the AQ patient and clinician rating indicated that no participants fell in the clinically significant range for impaired self-awareness (Evans et al. 2005). However, nine participants scored between 10 and 20 points higher than the clinician rating, indicating scores approaching the clinical level. Descriptive statistics also indicated a range of awareness levels in the sample. 11 participants had a negative score for AQ discrepancy indicating that they had a potentially over inflated estimation of their difficulties.

Mean score for Depression (HADS) fell within the 'borderline' range with 10 participants meeting the clinical range for depression. Descriptive statistics for measures are outlined in Table 2.

Table 2. Descriptive statistics of neuropsychological measures

N=25	Minimum	Maximum	Mean	Standard Deviation
AQ Patient Form	21	53	34.12	8.51
AQ Clinician Form	27	46	34.84	4.47
AQ Discrepancy	-14	17	-.72	9.19
HADS Depression	3	17	8.96	4.07
TMT B-A	15	252	64.4	55.28
WCST Categories	0	6	5.08	1.77
WCST Perseverative Errors	4	68	16.4	14.61

Note. AQ = Awareness Questionnaire, HADS = Hospital Anxiety and Depression Scale, WCST = Wisconsin Card Sorting Test, TMT = Trail Making Task.

The hierarchical multiple regression was run with eight combinations of variables in total as described above. Regardless of the order of the variables entered into the regression analysis, TMT discrepancy was consistently shown to contribute a statistically significant proportion of the variance in the dependant variable (p = .014 to .039). HADS depression was also shown to consistently contribute to the model regardless of the order of variables entered into the analysis (p = .001 to .015). WCST scores (categories and perseverative errors) were consistently found not to be significant predictors of the dependant variable, regardless of the order in which they were entered into the regression model (p = .250 to .962). The amount of variance accounted for by the regression models ranged from 17.0% (model one) to 61.9% (model 4; see Table 3).

Table 3. Each regression model with corresponding R^2 value

Model	R^2
1. Demographics	.170
2. Demographics + Depression	.479
3. Demographics + Depression + WCST scores	.454
4. Demographics + Depression + TMT Discrepancy	.619**
5. Demographics + WCST scores	.237
6. Demographics + WCST scores + TMT Discrepancy	.403
7. Demographics + TMT Discrepancy	.325
8. Demographics + Depression + TMT Discrepancy + WCST scores	.616

Note. HADS = Hospital Anxiety and Depression Scale, TMT = Trail Making Task, WCST = Wisconsin Card Sorting Test. ** = the best fitting regression model.

According to analysis of F change values (F^2), the best fitting model was Model 4 (see Table 3). Demographics were entered into step one of the analysis which accounted for 17% of the explained variance in the dependant variable (AQ discrepancy), but was not found to be a significant contributor to the variance ($F^2_{(2, 22)} = 2.247$, $p = .129$). The introduction of HADS depression at step two was found to increase the variance of the model to 47.9% and explained a significant amount of the variance over and above demographic information alone ($F^2_{(1,21)} = 12.495$, $p = .002$). Finally, the introduction of the TMT discrepancy at step three was again found to significantly increase the variance of the regression model to 61.9% and explained a significantly higher proportion of the variance over and above steps one and two ($F^2_{(1,20)} = 7.314$, $p = .014$).

Further examination of the variables in the best fitting regression model (model 4) confirmed that depression ($t_{(24)} = -3.924$, $p = .001$) and TMT discrepancy ($t_{(24)} = -2.704$, $p = .014$) were significant predictors of AQ discrepancy over and above the other variables' contribution to the model. The direction of the relationship demonstrated that higher levels

of depression were associated with increased self-awareness and more difficulty set shifting on the TMT was associated with reduced levels of self-awareness. Education was also found to be a significant predictor in the final model ($t_{(24)} = 2.987$, $p = .007$) with increased years of education being associated with reduced levels of self-awareness (see Table 4).

Table 4. Coefficients of best fitting multiple regression model

	B	Std. Error	β	t	Sig.
Constant	-13.382	9.708	-	-1.378	.183
Age	-.091	.115	-.113	-.792	.437
Education	1.845	.618	.415	2.987	.007*
HADS Depression	-1.256	.320	-.556	-3.924	.001*
TMT Discrepancy	.063	.023	.376	2.704	.014*

Note. HADS = Hospital Anxiety and Depression Scale, TMT = Trail Making Task. * = significant at the .05 level.

DISCUSSION

Consistent with previous research (Malec et al., 2007; Wallace & Bogner, 2000), the current study found that awareness was negatively associated with self-reported levels of depression. Contrary to previous research (Bivona etal., 2008; Noe et al., 2005) the current study failed to find any significant relationships between the WCST and levels of self-awareness, but this was consistent with some previous research (Bach and David, 2006; O'Keefe et al., 2007). Interestingly, the current study also found that set shifting, as measured using the TMT was a significant predictor of self-awareness. The multiple regression model confirmed that depression and the TMT discrepancy were contributing independently to the explained variance in the AQ discrepancy score.

The current study provides partial support for general disorder theories of self-awareness which suggest that disruption to higher order executive cognitive skills lead to deficits in self-awareness. (Mesulam, 1985; Shallice & Burgess, 1991; Stuss, 1991). However the theory does not specify which elements of executive function may be able to explain deficits in self-awareness. There is some empirical support for general disorder theories finding associations between measures of executive function and measures of self-awareness (Allen & Ruff, 1990; Bivona et al., 2008; Malec, Machulda & Moessner, 1997; Noe et al., 2005; Ownsworth, McFarland & Young, 2000; Starkstein et al., 1993; Trudel, Tryon & Purdum, 1998). The studies use various measures of executive function and self-awareness, so it is impossible to draw any firm conclusions from these findings. The current study focused on measures of flexibility, inhibition and set shifting. Interestingly the only significant predictor of self-awareness was set shifting, which suggests in this sample that a specific element of executive function is related to self-awareness, as opposed to the inclusive general disorder theories. It is plausible that if someone struggles to re-direct their attention (set shifting) then it would be more difficult to shift towards external stimuli informing the person of acquired difficulties.

In line with previous research, the current study demonstrated an association between reduced self-awareness and lower levels of reported depression (Fleming, Strong & Roderick, 1998; Malec et al., 2007; Wallace & Bogner, 2000). Psychologically based theories of self-awareness propose that because awareness is qualitatively different between each person, impaired self-awareness can be attributed to a combination of pre-morbid personality, coping style and post-injury personality (Giacino & Cicerone, 1998; Ownsworth et al., 2000). Potentially the significant finding of years of education found in this study could contribute to these pre-morbid factors that are thought to influence self-awareness. These theories

however reject the influence of neuropsychological factors in explaining different levels of self-awareness.

The results from the current research would be more in line with integrated theories of self-awareness which recognise that there are numerous ways in which each person with a brain injury adapts and represents themselves (Ownsworth et al., 2000). The presentation of a person with reduced self-awareness varies enormously so it is possible that a number of factors contribute to the development and maintenance of impaired self-awareness. Allen & Ruff (1990) proposed that there are three distinct levels of processing that allow humans to have accurate self-awareness. The first level requires the individual to attend to information about the self which would naturally be vulnerable to neuropsychological deficits. The second level requires the individual to 'appraise' the information about the self and compare it to pre-morbid functioning. The final level involves the willingness of the individual to disclose such information to another person. The authors propose that the final two levels are vulnerable to both psychological and neuropsychological factors. The ability to self-monitor will naturally be affected if an individual struggles to set shift (Borkowski, 1996; Hacker, 1998; Schneider, 1998). With support, individuals may be able to identify difficulties, but potentially, will not be able to shift to new strategies or adjust their performance accordingly (Toglia & Kirk, 2000).

The present study found that 44% of participants (n=11) reported more difficulties following their brain injury on the AQ compared to their clinician's rating. Overestimation of difficulties following brain injury has been linked to more mild brain injury (Jamora, Young and Ruff, 2011) and to co-morbid major depression (Chamelian & Feinstein, 2006). In the context of Allen & Ruff's (1990) model described above, it is possible that these

participants are somewhat hypervigilant to changes in their functioning following ABI which will naturally influence levels one and two in the model. To understand the nature of this relationship more fully is beyond the scope of the present study. More data will be needed to be able to make reliable comparisons between subgroups within the data. It does however highlight the clinical importance of fully understanding each individual's subjective experience of their functioning following ABI.

Limitations

The present study was subject to a few limitations. Firstly, it should be noted that with a small sample size (n=25), the researchers were limited as to the number of variables which could reliably be entered into the regression model, due to the risk of 'over-fitting' the model. Smaller sample sizes are also subject to inflated type II errors where only the largest associations between variables are detected. It is likely that the current study was underpowered due to a slightly smaller sample size than required by the power analysis. Continuing to collect data would allow the researchers to make more reliable predictions regarding the relationships described above. The participants included in the sample also had mixed aetiologies which could be argued as reducing external validity due to heterogeneity. It was also not possible to assess each participant's pre-morbid experience of depression which may act as a confounding variable. The cross-sectional nature of the study also means that it is impossible to make any assumptions regarding changes in self-awareness and the relationship with depression and executive function over time, or any causative relationships. More tightly controlled longitudinal studies with larger sample sizes would allow further insight into these relationships. Nevertheless, the current study consisted of a real world clinical sample representative of individuals presenting at community brain injury rehabilitation services.

Conclusion

In conclusion, the results from this investigation raise important considerations for clinical practice. Firstly, levels of self-awareness are still variable in the post acute (>1 year) stages of ABI and thus it is important to continue to monitor awareness in community settings, as well as inpatient settings due to the negative impact on rehabilitation. Also, 44% of the sample (n=11) reported an overestimation of their difficulties so it is vital to gain a comprehensive understanding of patients' perceptions of their difficulties following ABI. Secondly, it is likely that both higher order neuropsychological and psychological factors contribute to the development and maintenance of impaired self-awareness. As discussed above, it is possible that the ability to set shift is fundamental to accurate self-monitoring and subsequently self-awareness. TMT is a classic test of set shifting and is quick and easy to administer, making it a useful tool to monitor set shifting performance over time. It is important for clinicians to monitor patients' functioning in the above areas to further understand how people perceive changes in function following ABI in a person-centred manner.

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Chapter 3 – Contributions to Theory and Clinical Practice

Implications for future research and theory

The current meta-analysis aimed to answer the question; *is physical exercise an effective intervention to reduce depressive symptoms following acquired brain injury (ABI)?* In line with previous research utilising exercise as an intervention to treat depression in non-ABI populations, the current meta-analysis found a small to medium main effect (Krogh, Nordentoft, Sterne & Lawlor, 2010; Mead et al., 2009). The empirical paper aimed to further understand the relationship between self-awareness, depression and executive function in people with ABI. The results suggested that both depression and executive function (in particular set shifting) were related to self-awareness and accounted for different proportions of the variance within the self-awareness measure. The current paper aimed to bring together the meta-analysis and the empirical paper to demonstrate how both separate but fundamentally linked pieces of research contribute to current psychological theory regarding self-efficacy and implications for clinical practice.

Self-efficacy can be described as the belief and amount of confidence a person feels to accomplish certain tasks or to succeed in situations (Bandura, 1997). It has been proposed that self-efficacy may be one mechanism which could explain why physical exercise can help to reduce depressive symptoms (Craft, 2005). People with depression often experience low self-efficacy and Bandura (1997) describes how low self-efficacy will often lead to more negative ruminations and self-evaluations. People with depression will often internalise blame for negative events which serves to maintain the depressive symptoms (Peterson & Seligman, 1984). Clearly, multiple sources of information will inform each person's efficacy beliefs, but the most reliable source appears to come from experiences of mastery. If an individual is able to repeatedly achieve the desired outcome despite changes in situation and

different obstacles that present themselves, they are likely to experience feelings of mastery and thus higher self-efficacy (Craft, 2005). On the opposing end of the continuum, if an individual experiences multiple failures to achieve desired outcomes, this will lead to reduced feelings of self-efficacy.

Alongside the obvious health benefits, physical exercise has the potential to be an effective strategy to enhance self-efficacy beliefs due to the potential for experiencing mastery of meaningful activities. Interventions intended to improve self-efficacy focus on teaching the person to monitor their own behaviour, setting realistic and achievable goals and using appropriate social support to keep desired behaviours going (Bandura, 1997). In regard to physical exercise interventions, learning to set appropriate exercise goals and to monitor own exercise behaviour alongside encouragement and support from an instructor will all naturally lead to feelings of mastery and thus increased self-efficacy (Craft, 2005). It is therefore plausible that the reduction of depressive symptoms following physical exercise interventions may be related to experiences of mastery.

The ability to self-monitor is a key factor to facilitate increased self-efficacy. As discussed in the empirical paper, altered levels of self-awareness following ABI are common (Schacter, Glisky & McGlynn, 1990; Sherer, Hart & Nick, 2003) and can manifest in an overestimation of one's abilities, which can lead to reduced self-efficacy (Bandura, 1977; Gage, & Polatajko, 1994). Overestimation of abilities can lead to outcomes or results which were unexpected and can lead to insecurity for the individual who will not know whether things will turn out right or wrong (Toglia & Kirk, 2000). This uncertainty can result in feelings of confusion, loss of control, emotional distress and ultimately avoidance. Alternatively, blame may be put on external sources, again leading to avoidance but also

potentially hostility and isolation (see Figure 1 for a graphical representation). Ultimately, either reaction will lead to a reduction in self-efficacy (Bandura, 1997; Cotrell, 1997; Hibbard, Gordon, Stein, Grober & Sliwinski, 1992; Toglia & Kirk, 2000).

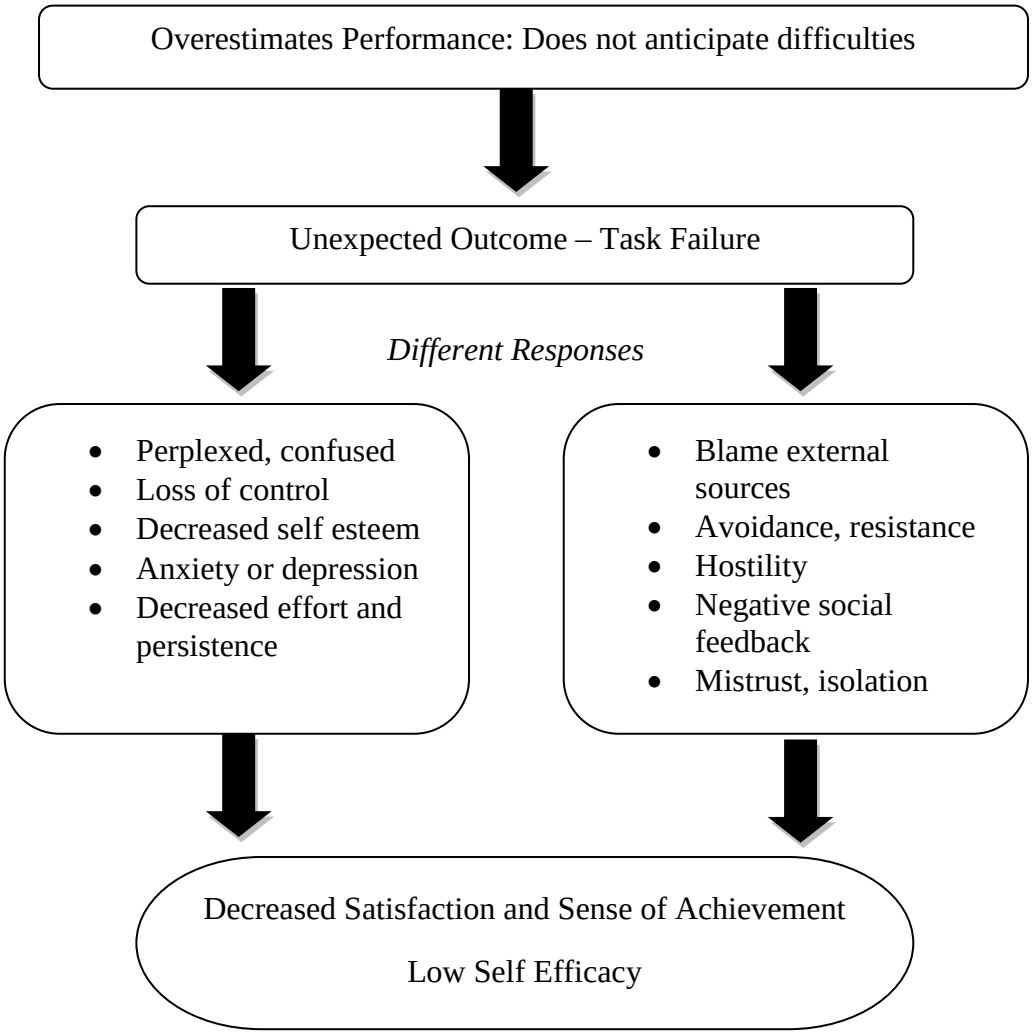

Figure 1. Overestimation of performance lowers self-efficacy. Adapted from Toglia & Kirk (2000)

The model of self-efficacy discussed provides a potential psychological explanation as to why physical exercise has been found to have a small to medium anti-depressant effect in people with (see current meta-analysis) and without ABI (Krogh, Nordentoft, Sterne &

Lawlor, 2011; Mead et al., 2008). The empirical paper also provides a further insight into the factors that could interrupt the process of increasing self-efficacy. The empirical paper found that reduced self-awareness (or overestimation of abilities) is related to difficulties with set shifting. If an individual has difficulty shifting between different sources of information, naturally we would expect them to have difficulty self-monitoring. This will be important to take into account when considering interventions to increase self-efficacy which will rely on the individual being able to monitor their behaviour and performance. As with the intervention studies included in the meta-analysis (Bateman et al., 2001; Bellon et al., 2015; Chin, Keyser, Dsurney & Chan, 2015; Damiano, Zampieri, Acevedi & Dsurney, 2016, Driver & Ede, 2009; Lee, Ashman, Shang & Suzuki, 2014; Rzezak et al., 2015; Schwandt et al., 2012; Weinstein et al., 2016; Wise, Hoffman, Powell & Bombadier, 2012) it is important to adapt interventions appropriately for people with ABI. This could be in the form of additional feedback to scaffold self-monitoring, help setting and remembering realistic goals or psycho-education regarding the consequences of ABI. Future research should concentrate on further controlled trials to understand the anti-depressant effect of exercise post ABI. Routinely collecting data regarding self-efficacy, awareness and depression will help to further understand the possible associations discussed above.

The empirical paper found that a significant proportion (44%) of participants actually over estimated their difficulties and acknowledged that investigating further this finding was beyond the scope of the study. Future research should aim to recruit a larger participant sample to allow sufficient power to analyse the subgroup of participants overestimating their difficulties and to assess whether there is anything unique about this group compared to those who are either in-line with clinician ratings or underestimating their difficulties (decreased awareness). It would be interesting to look at the nature and severity of the brain injury and

depression measures as these have both been linked with overestimation of difficulties in previous research (Chamelian & Feinstein, 2006; Jamora, Young and Ruff, 2011).

Implications for clinical practice

The findings from the current meta-analysis provide some support for the use of physical exercise as an intervention to reduce depressive symptoms following brain injury. Fann et al. (2009) conducted a telephone survey and the Patient Health Questionnaire with 145 adults within 12 months of being admitted with mild to severe traumatic brain injury (TBI). During the telephone interview, patients were asked about willingness to participate in different treatment modalities should they experience depression in the future. The sample consisted of 37 patients classed as experiencing depression as according to the Patient Health Questionnaire and 108 patients who did not report elevated depressive symptoms. 84% of the sample indentified physical exercise as the treatment of choice above all others (psychotherapy, alternative medicine, self-help, anti-depressants and support groups). This finding alongside the small to medium antidepressant effect of physical exercise following brain injury (current meta-analysis) provides support for the use of physical exercise as a clinical intervention to help with depression following brain injury. It will be important that exercise interventions are conducted in a person-centred manner, taking into account each individual's physical and cognitive needs. It may be necessary to provide extra support to remind patients to complete exercise between supervised sessions and to ensure that instructions are appropriate for each individual's level of comprehension.

Since 2007, across Wales the Welsh Assembly Government has funded the 'National Exercise Referral Scheme' (NERS), a scheme whereby health professionals can refer their patients to a local gym to use the exercise equipment in a supervised and individualised exercise plan. The current meta-analysis and qualitative data described above (Fann et al., 2009) provides further support for this scheme for people with an ABI. Increasing physical activity will have obvious health benefits as well as the potential to increase self-efficacy and reduce depressive symptoms. Depression often leads to avoidance and subsequently isolation, therefore attending a public gym will also go some way to combating the social isolation that many people with ABI face. Only 10 studies met the inclusion criteria for the meta-analysis. It will be important for future research to continue to investigate the use of physical exercise as an intervention for depression following ABI, to provide further evidence for its use in clinical settings.

The results from the empirical paper are also important to take into account when considering the use of physical exercise as an intervention to reduce depressive symptoms following ABI. As discussed, deficits in self-awareness following ABI are common and the current empirical paper demonstrated that self-awareness levels can still vary many years following ABI (one to 43 years). Monitoring self-awareness will allow clinicians to tailor exercise programmes and recommendations to ensure they are appropriate for the individual, alternatively, if self-awareness is severely impaired then a behavioural exercise programme may not be appropriate at that time.

The empirical paper also raises wider clinical implications in regard to our understanding of the mechanisms underlying self-awareness. The current results indicated that a specific higher order cognitive function (set shifting) is related to different levels of

self-awareness whereby people who demonstrated less self-awareness had more difficulty in set shifting. Theories acknowledge that both higher order cognitive function and psychological distress are likely to play a role in the development and maintenance of altered levels of self-awareness (Allen & Ruff , 1990; Ownsworth et al., 2000) but fail to identify specific neuropsychological functions that may be related. More research is required to replicate the findings of the current study. However, when engaging individuals with ABI in rehabilitation it would be prudent to monitor levels of self-awareness with all available sources of information, and to be aware and monitor potential deficits in set shifting. Due to the detrimental effect of reduced self-awareness on rehabilitation goals (Allen & Ruff, 1990; Askenasy & Rahmani, 1987; Prigantio, 1988; Groswasser, Mendelson, Stem, Schechter & Najenson, 1977; Najenson et al., 1975; Schachter, Gilsky & McGlynn, 1990), clinicians may be able to tackle this by supporting the individual to self-monitor and scaffold the process of shifting between internal and external feedback, with the ultimate goal of improving self-awareness and subsequently engagement in restorative and compensatory rehabilitation strategies. It is also important to recognise when individuals might be overestimating their difficulties following a brain injury as demonstrated with 44% of the participants in the empirical research paper. Rehabilitation following ABI tends to concentrate on compensating for acquired difficulties by placing more reliance on intact skills. To ensure rehabilitation is person centred and effective, firstly the clinician and the individual need to understand the individual's strengths and weaknesses. If the individual is over estimating their difficulties then it will be important to engage in psycho-education and potentially some behavioural experiments to ensure the individual can then engage fully in the most effective rehabilitation strategies.

When attempting to quantify an abstract concept such as self-awareness, it is important to carefully consider the tools used and the limitations of such a process. The empirical paper utilised the Awareness Questionnaire (AQ; Sherer et a., 1998) which consists of three forms; patient, significant other and clinician. The AQ requires the respondent to rate their own or the person with the ABI's functioning in different areas compared to pre-injury levels. The current study analysed the discrepancy between the patient and clinician ratings whereby a higher discrepancy constitutes more impaired self-awareness (Evans et al., 2005). This works on the assumption that the clinician's rating of the individual is in fact potentially more accurate than the individual's rating of him or herself. It is important to recognise that most clinicians will form a relationship with a patient only after they have acquired a brain injury (and not before). Therefore, the clinicians' comparisons to pre-injury levels are likely based on reports from the patient, significant others and estimations from neuropsychological test data. However, these sources of information are certainly not universally available to each clinician and regarding each patient. This puts into question the consistency with which clinicians can be expected to draw comparisons between pre and post injury functioning. Any measure attempting to capture an abstract concept such as self-awareness is going to have its limitations. It is important to interpret the AQ with an appropriate amount of caution and acknowledge the limitation of using multiple subjective questionnaires to measure the concept of self-awareness. The AQ is not alone in its reliance on the discrepancy between ratings to make judgements on levels of self-awareness following injury (Fleming, Strong & Ashton, 1996; Sherer, Hart & Nick, 2003) and it was deemed an appropriate measure to use for the current study (Carroll & Coetzer, 2011; Sherer et al., 1998). To try to account for some of the limitations, the current study would have benefitted from collecting AQ data from significant others in addition to that from the clinician to allow as accurate measure as possible of the individuals' functioning pre and post ABI. The current

author would also recommend that future research utilising the AQ endeavour to collect data from the individual themselves as well as two informants.

Reflective Commentary

When the time came to decide in which area of psychology to conduct my DClinPsy research, for me, it was simple. Since completing a single module in 'Cognitive Neuroscience' in my undergraduate degree in 2005, I was hooked and did not hesitate when I secured the funds to complete a Master's degree in neuropsychology. Throughout my clinical training I have tried to remain open minded when experiencing core placements in other disciplines but my core instinct always drew me back to neuropsychology. I have often reflected upon what it is about this subject that resonates so strongly with me, it is not something that has touched me on a personal level. Having the wonderful opportunity to utilise the personal and professional development therapy vouchers provided me with another aspect upon which to reflect. It was in this forum that it was suggested to me that having something concrete to identify on a scan was somehow safer to me than the unpredictability of general mental health services. For me though, I am genuinely fascinated by brain-behaviour relationship and the varied changes that occur following an acquired injury but also the incredible resilience I have witnessed working with people across the lifespan. Maybe there is an element of safety there that stems from 12 years of interest, academia and work in the field.

Even before the data collection started I was acutely aware of the potential burden I was placing on busy clinicians in the service from which I was hoping to recruit. The approved ethics stated that participants were to be approached by their treating clinician in

the first instance. This left me in a position of relying on already very busy clinicians to a) remember to ask and b) choose to ask patients from their current case load if a researcher could contact them at a later date. Being all too aware of pressures on clinicians, this was a process that made me feel uncomfortable. However, I was heartened by the response from my colleagues who recalled their own training and the pressures to recruit participants. I suspect in a similar process to the individuals who participated in my research, the clinicians kindly recruiting on my behalf felt in some way it was a process of giving back, having been through their own training. Indeed it is a position that I hope to be in, in the near future, to aid my successors.

The process of collecting data for my empirical paper highlighted to me the importance of utilising my clinical skills and experiences. I was always acutely aware that each individual had voluntarily given up their time to contribute to my research, and each and every person deserved the utmost respect, and the chance to tell their own story. My clinical experience also informed me when it was important to cease testing where the person's wellbeing of course over ruled the desire to collect more data. This did however raise further points of reflection in regards to a temptation to slip into 'therapist mode'. I chose to complete a specialist clinical placement in the service alongside collecting data for my research, which I felt sometimes further blurred the line between trainee clinician and researcher. Often, what had the potential to be a one hour appointment quickly over-ran when I was all too happy to be engulfed in each person's narrative of their experiences, and I was struck by the therapeutic advantages this appeared to have for the participants.

By far the most frustrating part of conducting this research was the geographical distance covered to meet with each participant. It was not uncommon to drive an hour and a

half to what was often a one hour appointment, and of course it rarely worked out that two people who lived nearby were available on the same day. That said, any frustrations I did feel immediately dissipated when I met those who had kindly agreed to participate. Overwhelmingly, I was welcomed into homes and received stories of gratitude towards the North Wales Brain Injury service. Any concerns I had about taking up people's free time were alleviated by the rewards that each person clearly experienced being able to 'give something back' for the care that they had received.

Regular supervision allowed me ample opportunity to reflect upon my clinical and research work including the frustrations and rewards. I often found myself discussing research participants with their treating clinician, feeling the need to pass on the gratitude they expressed for their care, or taking the extra time to deliver a gift I was asked to pass on. I felt that after each person voluntarily gave up their time to inform my research, the least I could do was to pass on their wishes in a process of conveying my own gratitude.

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Appendices

I. Bangor University, School of Psychology Ethics Committee Approval

II. NHS IRAS Research Ethics Committee Form

III. Research Ethics Committee Amendments and Approval Letter

IV. Research & Development Approval Letter

V. Participant Consent Form – English

VI. Participant Consent Form – Welsh

VII. Participant Information Sheet – English

VIII. Participant Information Sheet – Welsh

IX. Awareness Questionnaire (AQ)

X. Hospital Anxiety and Depression Scale (HADS)

XI. Trail Making Task A & B (TMT)

XII. Wisconsin Card Sorting Test (WCST) Record Form

Appendix I

Bangor University, School of Psychology Ethics Committee Approval

Sophie Perry

From: ethics@bangor.ac.uk
Sent: Monday, February 22, 2016 1:39 PM
To: Sophie Perry
Subject: Ethical approval granted for 2016-15617 An exploration of insight, executive function and psychological distress following acquired brain injury (ABI).

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Sophie,

2016-15617 An exploration of insight, executive function and psychological distress following acquired brain injury (ABI).

Your research proposal number 2016-15617 has been reviewed by the Psychology Ethics and Research Committee and the committee are now able to confirm ethical and governance approval for the above research on the basis described in the application form, protocol and supporting documentation. This approval lasts for a maximum of three years from this date.

Ethical approval is granted for the study as it was explicitly described in the application

If you wish to make any non-trivial modifications to the research project, please submit an amendment form to the committee, and copies of any of the original documents reviewed which have been altered as a result of the amendment. Please also inform the committee immediately if participants experience any unanticipated harm as a result of taking part in your research, or if any adverse reactions are reported in subsequent literature using the same technique elsewhere.

Appendix II

NHS IRAS Research Ethics Committee Form

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
The psychological and cognitive correlates of insight following ABI

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

(●) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

☐ England
☐ Scotland

☑ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

○ England
○ Scotland
◉ Wales
○ Northern Ireland
○ This study does not involve the NHS

4. Which review bodies are you applying to?

☐ HRA Approval
☑ NHS/HSC Research and Development offices
☐ Social Care Research Ethics Committee
☑ Research Ethics Committee
☐ Confidentiality Advisory Group (CAG)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):

The present research is being undertaken to fulfill the requirements of the Doctorate in Clinical Psychology (DClinPsy). The student/trainee is an employee of Betsi Cadwaladr University Health Board (BCUHB). The trainee will be directly involved in recruiting participants, testing of participants, analysis of data and write up.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

(●) Yes ( ) No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

( ) Yes (●) No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

( ) Yes (●) No

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

NHS Health Research Authority

Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
The psychological and cognitive correlates of insight following ABI

Please complete these details after you have booked the REC application for review.

REC Name:
Wales REC 5

REC Reference Number:
16/WA/0085

Submission date:
25/02/2016

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

An exploration of insight, executive function and psychological distress following acquired brain injury (ABI)

A2-1. Educational projects

Name and contact details of student(s):

Student 1

Title	Forename/Initials	Surname
Mrs	Sophie	Perry

Address: North Wales Clinical Psychology Programme, 43 College Road, Gwynedd
Post Code: LL57 2DG
E-mail: psp4f1@bangor.ac.uk
Telephone: 07772564365
Fax:

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctorate in Clinical Psychology (DClinPsy)

Name of educational establishment:
Bangor University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Dr	Rudi	Coetzer
Address	North Wales Brain Injury Service		
	Colwyn Bay Hospital		
	Hesketh Road		
Post Code	LL29 8AY		
E-mail	Rudi.Coetzer@wales.nhs.uk		
Telephone	01492807770		
Fax	01492807770		

Academic supervisor 2

	Title	Forename/Initials	Surname
	Dr	Mike	Jackson
Address	North Wales Clinical Psychology Programme		
	43 College Road, Bangor University		
	Bangor, Gwynedd		
Post Code	LL57 2DG		
E-mail	Mike.Jackson@bangor.ac.uk		
Telephone	01248388746		
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Mrs Sophie Perry	☑ Dr Rudi Coetzer ☑ Dr Mike Jackson

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- ◉ Student
- ○ Academic supervisor
- ○ Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Mrs	Sophie	Perry
Post	Trainee Clinical Psychologist		
Qualifications	BSc (Hons) Psychology, University of the West of England, 2008 MSc Neuropsychology, University of Bristol, 2009		
Employer	Betsi Cadwaladr University Health Board (BCUHB)		
Work Address	North Wales Clinical Psychology Programme		
	School of Psychology, Bangor University		
	Bangor, Gwynedd		
Post Code	LL57 2DG		
Work E-mail	psp4f1@bangor.ac.uk		
* Personal E-mail	psp4f1@bangor.ac.uk		
Work Telephone			
* Personal Telephone/Mobile	07772564365		
Fax			

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Mr	Hefin	Francis
Address	School of Psychology		
	Brigantia Building, Penrallt Road,		
	Bangor University, Bangor		
Post Code	LL57 2AS		
E-mail	h.francis@bangor.ac.uk		
Telephone	01248388339		
Fax	01248382599		

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	2016-15617
Sponsor's/protocol number:	N/A
Protocol Version:	1
Protocol Date:	01/11/2015
Funder's reference number:	N/A
Project website: N/A	

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

Self-awareness in this context refers to the ability of the individual with an acquired brain injury (ABI) to recognise difficulties caused by their brain injury. Deficits in self-awareness are common following ABI and have been reported as causing the most impact on quality of life according to caregivers (Ergh, Rapport, Coleman & Hanks, 2002). Impairments in self-awareness can also impact on the individual's ability to engage with rehabilitation (Malec & Moessner, 2000). It has been proposed that lower levels of self-awareness following ABI may be linked to difficulties in executive function which is an umbrella term for skills such as planning, organising, initiating, monitoring and changing behaviour. There have been mixed findings in the literature regarding the potential link between deficits in executive function and level of self-awareness (e.g. Bogod et al., 2003; Noe et al., 2005; O'Keefe et al., 2007). The current study aims to explore further the links between executive function using standardised, validated cognitive tests and self-awareness. Furthermore the study will explore whether there are any links with low mood or anxiety. It is important to further understand self-awareness as it can have such a negative impact on the person with the brain injury and their family. Better understanding may enable us to tailor rehabilitation more effectively as reduced self-awareness can lead to poor engagement with rehabilitation (Malec & Moessner, 2000). Patients attending the North Wales Brain Injury Service (NWBIS) with an ABI that occurred at least one year previously would be eligible to participate. Participants will likely be enrolled in the study for up to 12 months and participation would include completing cognitive tests (paper and pencil type tests designed to measure thinking and reasoning skills) and questionnaires that should take no more than two hours.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Design and Procedures:
The study will employ a cross-sectional, correlational design. Correlation coefficients will be calculated to explore associations between cognitive and psychological functioning, and self-awareness. Dependent variables will be the outcome scores for the measures employed.

Participants will be asked to complete self report questionnaires pertaining to the symptoms of depression and anxiety, and perceived cognitive ability. Participants will also be asked to complete a number of standardised cognitive assessments to look at elements of executive function. Measures will be administered in one session (or two at the participant's request) and will take between 1-2 hours. Participants will be recruited from the North Wales Brain Injury Service (NWBIS) which is a multi disciplinary community based outpatient brain injury rehabilitation service.

Recruitment Procedure and Consent:
The Chief Investigator (CI; Sophie Perry) will approach clinicians at NWBIS and present the research proposal. Clinicians will be asked to identify clients on their case load that meet inclusion criteria. Clinicians will not approach clients on their case load whom do not have capacity to provide informed consent. These potential participants will be approached in the first instance by their treating clinician and asked if they would like a participant information sheet and if they consent to the CI contacting them by telephone approximately 1 week later to discuss the research. Participants who agree to be contacted will be given the opportunity to ask any questions about the research and to discuss the study. They will be asked if they would like to participate in the study. Prior to inclusion in the study, each participant will give their fully informed, written consent to participate. For those who take part in the study, a full debrief at the end of the testing session will be offered and further feedback session outlining the results of the tests if the participant is interested. All participants will receive a newsletter at the end of the study outlining the general findings. The CI will take primary responsibility for recruiting and testing participants when consent has been given. Where possible, testing will take place at the NWBIS but if participants are unable to attend, home visits or using the GP surgery will be offered. Participant travel expenses will be reimbursed when participants are travelling to and from NWBIS for the study.

Risks, Burdens and Benefits:
Potential risks include those related to lone working for the CI who may be required to undertake testing at the participant's home address. Where possible, lone working will be avoided and it is anticipated that the majority of testing will take place at the NWBIS or GP Surgery. When lone working is necessary, the Betsi Cadwaladr University Health Board Lone Worker Policy will be adhered to.
Treating clinicians at the NWBIS will be aware of any risks from the client to the CI and as such clients who represent a risk to the CI will not be approached.
The study has been deemed not to present any direct risks but participants will be asked questions about how their functioning has changed following their brain injury and questions about low mood and anxiety. Additionally participants may find the cognitive tests challenging and frustrating. If any participant experiences any distress they will be encouraged to speak to their treating clinician at the NWBIS or their GP. In circumstances where it is clear that the participant is experiencing significant distress, with the participant's consent, the CI will write to their GP via letter.

As participants will be completing a number of questionnaires and tests, any participant may request feedback on their results which will be given by the CI or the academic supervisor. If there are any concerns, these will be discussed with the participant's treating clinician at the NWBIS with the participant's consent to do so. If a participant experiences any distress as a consequence of taking part in the study, the participant will be advised to speak to their treating clinician at the NWBIS or their GP.

Benefits of taking part include contributing to the scientific evidence base and a full debrief on the study and individual tests if requested. Also a news letter detailing the findings of the research.

Burdens may include time spent participating in the study, reading the information sheet, the testing itself and talking with the CI.

Confidentiality:
All paper and electronic data will be stored at the NWBIS. Paper data will be stored securely in the client's file at NWBIS. Electronic data will be stored on a secure NHS networked computer at the NWBIS. Anonymised electronic data will be analysed on a password protected laptop and only made available to the CI and the Academic Supervisor. The CI will comply with BCUHB data protection policy and legislation. At the end of the project (July 2017) all data will remain securely at the NWBIS. All data will be destroyed after a specified time period in line with BCUHB policy. The data will be used for academic research publications in the form of journal articles and conference presentations (all data will be anonymous and presented as a group average). Participants will receive a brief news letter following completion of the research, alternatively they can request individual explanation of the results from the CI. Participant names will only be recorded once for consent purposes, following which, a unique identification number will be assigned and used thereafter and will be used exclusively if referring to specific data in research publications. Additional safeguards include keeping all consent forms and any paper copies of tasks or questionnaires in a locked filing cabinet at the NWBIS. Computer data will be stored annonymously on a password protected computer. All data and consent forms will be retained by the academic supervisor based at NWBIS following completion of the study for a minimum or 5 years, after which they will be safely disposed in line with BCUHB confidential waste policy.

A6-3. Proportionate review of REC application *The initial project filter has identified that your study may be suitable for proportionate review by a REC sub-committee. Please consult the current guidance notes from NRES and indicate whether you wish to apply through the proportionate review service or, taking into account your answer to A6-2, you consider there are ethical issues that require consideration at a full REC meeting.*

○ Yes - proportionate review ◉ No - review by full REC meeting

Further comments (optional):

Note: This question only applies to the REC application.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply.*

- [ ] Case series/ case note review
- [ ] Case control
- [ ] Cohort observation
- [ ] Controlled trial without randomisation
- [x] Cross-sectional study
- [ ] Database analysis
- [ ] Epidemiology
- [ ] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [ ] Qualitative research
- [x] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [ ] Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The main aim of this study is to determine if there are specific cognitive deficits secondary to ABI which contribute to the level of self-awareness the individual has. The first hypothesis predicts that lower levels of self awareness will be associated with deficits in executive functioning. The second hypothesis predicts that levels of self-awareness will be associated with psychological distress, in particular depression and anxiety and a poor functional outcome. Questionnaires pertaining to levels of self-awareness will be completed by the participant and their treating clinician at NWBIS. The participant will also complete questionnaires pertaining to features of depression and anxiety, and standardised cognitive tests assessing abilities in elements of executive function (particularly set shifting and perseveration).

Previous research has not assessed depression and anxiety alongside self-awareness and the link between executive function and self-awareness remains unclear. Deficits in self-awareness can cause significant distress for the client and their families and can restrict engagement in rehabilitation. Further understanding of the mechanisms contributing to deficits in self-awareness will inform treatment and potentially aid clinicians to better promote engagement in rehabilitation for individuals with reduced self-awareness.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

Not applicable

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Executive function (EF) refers to a plethora of complex and integrated cognitive processes that allow humans to "formulate goals; to initiate behaviours; to anticipate the consequences of action; to plan and organise behaviour according to spatial, temporal, topical or logical sequences; and to monitor and adapt behaviour to fit a particular task or context" (Cicerone et al., 2000; p1605). Impairments in executive function are common following ABI with one longitudinal study reporting 45% of participants' experiences deficits in EF following ABI up to 10 years post injury (Ponsford et al., 2014).

Self-awareness in this context refers to the ability of the individual with an ABI to recognise any difficulties caused by their brain injury. Deficits in self-awareness are common following brain injury and have been reported as causing the most impact on quality of life according to caregivers (Ergh, Rapport, Coleman & Hanks, 2002). Impairments in self-awareness can not only have an impact on quality of life for the individual with the ABI and their care givers but it can also impact on the individual's ability to engage with rehabilitation (Malec & Moessner, 2000).

Executive function and self-awareness
Various studies have explored correlations between executive dysfunction and impairments in self-awareness but the findings appear to be inconclusive.

Bach and David (2006) failed to find a correlation between executive dysfunction and reduced levels of self-awareness. Bogod et al. (2003) found a significant association between measures of executive function (Go-no-go task, the Victoria Stroop Test and the Self-Ordered Pointing Test) and the Self-Awareness and Deficit Interview (SADI). O'Keefe et al. (2007) in a group of 31 patients with TBI found no differences between participants with Low self-awareness and high self-awareness (as measured using the Awareness Interview-adapted) on neuropsychological tests of executive function (Verbal Fluency – FAS, Revised strategy Application Task, Frontal assessment battery) but they did find that those with low self-awareness were more likely to exhibit disinhibition, interpersonal difficulties and difficulties in competency. Noe et al. (2005) assessed executive function in 116 participants with ABI using the Wisconsin Card Sorting Test (WCST), and found a significant correlation between poor WCST performance (perseverative responses and number of categories) and low self-awareness. Bivona et al (2008) assessed 40 outpatients with severe traumatic brain injury and found a significant correlation between low self-awareness and performance on the WCST (specifically number of categories and number of perseverative responses) indicating that poor flexibility and decreased ability to inhibit a response may play a part in self-awareness.

The current study aims to explore further the links between executive function using standardised, validated cognitive tests and self-awareness. Furthermore the study will explore whether there are any links with low mood or anxiety. It is important to further understand self-awareness as it can have such a negative impact on the person with the brain injury and their family. Better understanding may enable us to tailor rehabilitation more effectively as reduced self-awareness can lead to poor engagement with rehabilitation (Malec & Moessner, 2000).

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Participants will be recruited from service users attending the NWBIS for routine outpatient appointments, identified by their clinician as having sustained a traumatic brain injury and who do not meet any of the exclusion criteria.

Clinicians will approach the individuals in the first instance and provide them with some verbal and written information. If the individual is interested, a time will be arranged for the researcher to phone them and to discuss the study further at a time of their convenience.

After the initial phone conversation, participants will be asked to let the researcher know within one week whether they would like to participate. If they would like to continue with the research a time will be made for the participant to attend the NWBIS to complete the testing. If the participant is unable to travel to the NWBIS then the researcher will arrange to meet the participant at their GP surgery or at their home. Travel expenses will be reimbursed when the participant is travelling to complete the testing. Participants should expect to be in the testing session for no more than 2 hours. The session will involve completing short questionnaires, answering questions about their experience following their injury and completing some paper and pencil type tasks to look at problem solving abilities. If the participant would rather complete the testing over two sessions, that can be arranged.

Once the tests are completed the participant will receive verbal feedback from the researcher on the testing and be offered more comprehensive feedback on the results of the tests at a later date if the participant would like. This can be given over the phone or the researcher can arrange to meet with the participant if they would rather.

Once the research has been written up, the researcher will create a newsletter to circulate to all participants outlining the general findings of the study. It is anticipated that this will be in June 2017.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

☐ Design of the research

- ☐ Management of the research
- ☐ Undertaking the research
- ☐ Analysis of results
- ☑ Dissemination of findings
- ☐ None of the above

Give details of involvement, or if none please justify the absence of involvement.
After completion of the study the CI will produce a newsletter for all participants which will be reviewed by the university 'People Panel' before dissemination.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Approximately 30 participants with a confirmed history of ABI will be prospectively recruited to participate. All participants will be recruited from the NWBIS. Participants who sustained an ABI with a minimum interval of one year following brain injury to exclude those who have only recently sustained injury. Severity of traumatic brain injury will be determined by examining patient's medical file following the Mayo Classification System (Malec et al., 2007).

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Patients will be excluded form participating in the current study based on the following criteria: severe cognitive impairment that would impair ability to participate (determined by the treating clinician at the NWBIS), inability to provide informed consent (this will be determined by the treating clinician), existing psychiatric condition (determined from the participant's clinical file), current substance misuse/dependence, time since injury less than one year.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Initial telephone consultation	1	0	20 minutes	Sophie Perry, CI at the NWBIS or clients home/ GP at their request.
Seeking consent	1	0	20 minutes	Sophie Perry, CI at the NWBIS or clients home/ GP at their request.
Trail Making Test A&B	1	0	10 minutes	Sophie Perry, CI at the NWBIS or clients home/ GP at their request.
Wisconsin Card Sorting Test	1	0	40 minutes	Sophie Perry, CI at the NWBIS or clients home/ GP at their request.
Awareness Questionnaire, Client version	1	0	5 minutes	Sophie Perry, CI at the NWBIS or clients home/ GP at their request.
Hospital Anxiety and Depression	1	0	15	Sophie Perry, CI at the NWBIS or clients home/ GP at their

Scale			minutes	request.
Debrief	1	0	15 minutes	Sophie Perry, CI at the NWBIS or clients home/ GP at their request.

A21. How long do you expect each participant to be in the study in total?

Up to 12 months

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Whilst no direct risks are anticipated, the study will take up to about two hours of each participant's time. There is a small possibility that participants might find some of the tasks more difficult than expected which can sometimes be frustrating or upsetting.

Participants will also be asked to complete a questionnaire about how they are feeling which can very occasionally bring distressing feelings to the front of ones mind.

Clients will be selected by their treating clinicians. The CI will explain each test and questionnaire in detail and clients will be aware that they are free to withdraw at any time without giving a reason. If any distress is caused as a direct result of the study, participants will be encouraged to speak to their treating clinician at the NWBIS or their GP. In extreme cases, the CI would seek the participant's consent to write directly to their GP.

The recruitment procedure whereby the treating clinicians at the NWBIS identify suitable potential participants from their caseload will prevent unsolicited communication regarding the study and will prevent individuals who are vulnerable or unsuitable being put forward.

Once the testing session has finished with each participant, they will receive a full debrief from the CI and additionally the option for a more extensive feedback about test results and/or a newsletter outlining the main results of the study.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

(●) Yes ( ) No

If Yes, please give details of procedures in place to deal with these issues:

Whilst the study is expected not to involve any direct risks to clients, questionnaires will ask directly about symptoms of depression and anxiety and difficulties following a brain injury. Clients will be selected by their treating clinicians, minimising the risk of inappropriate participants being put forward. The CI will explain each questionnaire in detail and clients will be aware that they are free to withdraw at any time without giving a reason. If any distress is caused as a direct result of the study, participants will be encouraged to speak to their treating clinician at the NWBIS or their GP. In extreme cases, the CI would seek the participant's consent to write directly to their GP.

A24. What is the potential for benefit to research participants?

Although there are no direct benefits to the individuals taking part in the study, participants will have the knowledge that they are contributing to the scientific evidence base to potentially improve rehabilitation in the future. Participants will be given a full debrief on the study and individual tests if requested. Also a news letter detailing the findings of the research.

A26. What are the potential risks for the researchers themselves? *(if any)*

Potential risks to the CI include those related to lone working as the CI may be required to undertake testing sessions at the participant's homes. Where possible this will be avoided and it is anticipated that the majority of testing will take place at the NWBIS or a GP practice local to the participant. Where lone working cannot be avoided, the BCUHB Lone Worker Policy will be adhered to. When clinicians approach their clients to participate in the study, they will screen out any clients who may pose a potential risk to the CI.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

In the first instance the CI will approach clinicians at NWBIS and present the project and answer any questions they may have. Clinicians will be asked to identify participants who meet the inclusion criteria from their current case load. Potential participants will be approached by their treating clinicians and asked if they would like a study information sheet and if they consent to the CI (Sophie Perry) contacting them approximately one week following via the telephone to discuss the study further and at this point potential participants will be asked if they wish to participate in the study. Prior to inclusion in the study, the CI will gain fully informed written consent to participate from each participant. Participants will be given the opportunity to discuss the research with the CI and ask any questions they may have. The CI will take responsibility for asking clinicians to identify potential participants and for testing once participants have agreed to take part.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

(●) Yes ( ) No

Please give details below:
Only members of the participant's clinical care team will have direct access to identifiable personal information in the individual's clinical file. the NWBIS clinician will screen the individual's clinical file to check for eligibility for the study. The treating clinician will then make the first contact with the potential participant to query whether they would be interested in taking part in the research and if so do they consent for the clinician to pass on their contact details to the CI who will contact them to discuss it further. The CI will ONLY contact the potential participants once she has been informed by the treating clinician that the individual is interested to hear more about the research study.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

( ) Yes (●) No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

( ) Yes (●) No

A29. How and by whom will potential participants first be approached?

In the first instance the CI will approach clinicians at NWBIS and present the project and answer any questions they may have. Clinicians will be asked to identify participants who meet the inclusion criteria from their current case load. Potential participants will be approached by their treating clinicians and asked if they would like a study information sheet and if they consent to the CI (Sophie Perry) contacting them approximately one week following via the telephone to discuss the study further and at this point potential participants will be asked if they wish to participate in the study. Prior to inclusion in the study, the CI will gain fully informed written consent to participate from each participant. Participants will be given the opportunity to discuss the research with the CI and ask any questions they may have. The CI will take responsibility for asking clinicians to identify potential participants and for testing once participants have agreed to take part. After the testing session, participants will be given the opportunity to discuss the process and ask any questions they may have. Where possible, participants will take part in testing at the NWBIS

and travel expenses will be reimbursed. If participants are unable to attend the NWBIS they will be given the option of participating in testing at a local GP or at their home address.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Only adults with the capacity to give informed consent will be approached. Consent will be given directly to the CI (Sophie Perry). Each participant will have a written information sheet accompanied by a verbal explanation of the study and the opportunity to ask any questions they may have. Additionally, the CI will arrange directly with the individual to contact them via phone approximately one week later and ensure they have the CI's contact details if they would like to make contact.

If you are not obtaining consent, please explain why not.

N/A

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

Approximately one week.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

Participants deemed not able to provide written informed consent will not be approached to take part in the study. Capacity will be decided upon by the treating clinicians at the NWBIS before contact details of those wishing to take part are passed on to the CI.

As the research is taking place in Wales ALL written documents will be provided bilingually but it will be explained that the CI is not a Welsh Speaker and that all measures are available in English only.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

Research documentation (i.e. participant information sheet, consent form, letter sent to participants) will be available bilingually. The battery of measures is only available and validated in English so participants will be made aware that tests and questionnaires will have to be carried out in English in order to maintain validated results. The CI is not a Welsh speaker so participants will be informed of this.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

○ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried

out on or in relation to the participant.

- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ◉ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

Patients who are deemed unable to provide informed consent will not be approached to take part in the research and as such continued capacity of those who have consented to participate will be assumed.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- ☑ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☐ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☐ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☑ Manual files (includes paper or film)
  - ☑ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☐ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:

The CI will access the clients medical notes to record details of the brain injury and brain scan findings.

Storage of personal data will confined to NHS computers and any paper containing personal information will be stored securely in the participant's clinical file at the NWBIS.

The telephone number of potential participants will be made available to the CI (Sophie Perry)only with the participant's consent. Home addresses will only be made available to the CI if the participant is unable to travel to the NWBIS or the GP and as such the CI would visit them at home, addresses will only be made available to the CI with the resident's consent.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

Each participant will be given a unique identification number which will be used for all paper and electronic data collected. Paper copies of questionnaires and test sheets will use the unique identification number only and will be stored in a locked filing cabinet in the NWBIS. A record of identification numbers will be kept in a separate locked location at the NWBIS and will only be accessible to the CI and the academic supervisor. Any data that is analysed electronically will be anonymous, using the unique identification number and will contain no personal identification information. Paper data will be retained at the NWBIS and will be destroyed in line with BCUHB policy on data management.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The research team (I.E. Sophie Perry and Dr Rudi Coetzer) will have access to participant's personal data during the study along with each patient's treating clinician.

Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

- (●) Less than 3 months
- ( ) 3 – 6 months
- ( ) 6 – 12 months
- ( ) 12 months – 3 years
- ( ) Over 3 years

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

(●) Yes ( ) No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
Participants will have their travel expenses to and from the NWBIS reimbursed. If participants wish to claim for travel expenses, they will be required to give the CI a receipt to allow the CI to reimburse the value of the journey.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

( ) Yes (●) No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

( ) Yes (●) No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

◉ Yes ○ No

Please give details, or justify if not registering the research.
The final thesis will be made available in the Bangor University research repository

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

☑ Peer reviewed scientific journals
☐ Internal report
☑ Conference presentation
☐ Publication on website
☐ Other publication
☐ Submission to regulatory authorities
☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
☐ No plans to report or disseminate the results
☑ Other (please specify)

A newsletter outlining the results of the study will be circulated to participants who took part in the study.

A53. Will you inform participants of the results?

◉ Yes ○ No

Please give details of how you will inform participants or justify if not doing so.
At the end of the study, a participant newsletter will be distributed to participants who took part in the study outlining the main results.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

☐ Independent external review
☐ Review within a company
☐ Review within a multi−centre research group

- [x] Review within the Chief Investigator's institution or host organisation
- [ ] Review within the research team
- [x] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The scientific quality of the study has been assured by the research team at the North Wales Clinical Psychology Programme and assessed as a suitable study as part of the doctoral programme. The study has also been reviewed by the School of Psychology Ethics Panel, and has received a favourable outcome.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- [ ] Review by independent statistician commissioned by funder or sponsor
- [ ] Other review by independent statistician
- [ ] Review by company statistician
- [ ] Review by a statistician within the Chief Investigator's institution
- [ ] Review by a statistician within the research team or multi−centre group
- [x] Review by educational supervisor
- [ ] Other review by individual with relevant statistical expertise
- [ ] No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Dr	Mike	Jackson
Department	North Wales Clinical Psychology Programme		
Institution	Bangor University		
Work Address	North Wales Clinical Psychology Programme		
	43 College Road, Bangor University		
	Bangor, Gwynedd		
Post Code	LL57 2DG		
Telephone	01248388746		
Fax			
Mobile			
E-mail	Mike.Jackson@bangor.ac.uk		

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

The study is correlational in nature with two hypotheses. The primary outcome measures are a) the neuropsychological test battery examining elements of executive function, b) the results from the anxiety and depression scale and c) the outcome of the Awareness Questionnaire discrepancy between the client and clinician rating.

A58. What are the secondary outcome measures? *(if any)*

N/A

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	30
Total international sample size (including UK):	0
Total in European Economic Area:	0

Further details:
Power analysis (based on previous findings, Bivona et al., 2008) indicates that for a correlational design, a sample size of 29 would be required to detect an effect size of 0.5. The CI will therefore aim to recruit between 30-40 participants.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

Power analysis (based on previous findings, Bivona et al., 2008) indicates that for a correlational design, a sample size of 29 would be required to detect an effect size of 0.5. The CI will therefore aim to recruit between 30-40 participants.

$N = [(Z\alpha + Z\beta) / C]^2 + 3 = 29$

Where:-
$\alpha = 0.05$,
$\beta = 0.2$,
$r = 0.5$,
$Z\alpha = \alpha$,
$Z\beta = \beta$,
$C = 0.5\ln[(1+r)/(1-r)] = 0.549$,

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Anonymised data will be analysed using SPSS. Correlations will be calculated to investigate associations between tests of executive function, measures of mood and anxiety and measures of self-awareness.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Dr	Rudi	Coetzer
Post	Consultant Clinical Neuropsychologist, Head of Service		

Qualifications	BA (cum laude), BA Hons Clin PSych (cum laude), MA Clin Psych (cum laude), D Clin Psy.
Employer	Betsi Cadwaladr University Health Board
Work Address	North Wales Brain Injury Service Colwyn Bay Hospital Hesketh Road
Post Code	LL29 8AY
Telephone	01492807770
Fax	01492807770
Mobile	
Work Email	Rudi.Coetzer@wales.nhs.uk

Title	Forename/Initials	Surname
Dr	Mike	Jackson

Post	Consultant Clinical Psychologist
Qualifications	BA, D Phil, D Clin Psy
Employer	North Wales Clinical Psychology Programme / Betsi Cadwaladr University Health Board
Work Address	North Wales Clinical Psychology Programme 43 College Road, Bangor University Bangor, Gwynedd
Post Code	LL57 2DG
Telephone	01248388365
Fax	
Mobile	
Work Email	Mike.Jackson@bangor.ac.uk

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	Bangor University
Given name	Hefin
Family name	Francis

Address	School of Psychology, Brigantia Building, Penrallt Road, Bangor University
Town/city	Bangor
Post code	LL57 2AS
Country	UNITED KINGDOM
Telephone	01248388339
Fax	01248382599
E-mail	h.francis@bangor.ac.uk

Is the sponsor based outside the UK?

○ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

☐ Funding secured from one or more funders

☐ External funding application to one or more funders in progress

☑ No application for external funding will be made

What type of research project is this?

○ Standalone project

○ Project that is part of a programme grant

○ Project that is part of a Centre grant

◉ Project that is part of a fellowship/ personal award/ research training award

○ Other

Other – please state:
Doctorate in Clinical Psychology

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

Title	Forename/Initials	Surname
Dr	Rosella	Roberts

Organisation	Betsi Cadwaladr University Health Board
Address	Clinical Academic Office, Clinical School, Ysbyty Gwynedd Bangor, Gwynedd

Post Code	LL57 2PW
Work Email	rossela.roberts@wales.nhs.uk
Telephone	01248384877
Fax	01248384877
Mobile	

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/06/2016
Planned end date: 30/06/2017
Total duration:
Years: 1 Months: 0 Days: 30

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☐ England
- ☐ Scotland
- ☑ Wales
- ☐ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study 1

Does this trial involve countries outside the EU?
○ Yes ◉ No

A72. Which organisations in the UK will host the research?*Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

- ☐ NHS organisations in England
- ☑ NHS organisations in Wales 1
- ☐ NHS organisations in Scotland
- ☐ HSC organisations in Northern Ireland
- ☐ GP practices in England
- ☐ GP practices in Wales
- ☐ GP practices in Scotland
- ☐ GP practices in Northern Ireland
- ☐ Joint health and social care agencies (eg community mental health teams)
- ☐ Local authorities
- ☐ Phase 1 trial units
- ☐ Prison establishments
- ☐ Probation areas
- ☐ Independent (private or voluntary sector) organisations
- ☐ Educational establishments

☐ Independent research units

☐ Other (give details)

Total UK sites in study: 1

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:* in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland**

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

UMAL Insurance

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

UMAL

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Research site		Investigator/ Collaborator/ Contact	
Institution name	Betsi Cadwaladr University Health Board	Title	Dr
Department name	North Wales Brain Injury Service	First name/ Initials	Rudi
Street address	Hesketh Road	Surname	Coetzer
Town/city	Colwyn Bay		
Post Code	LL29 8AY		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

◉ Chief Investigator

- ◯ Sponsor
- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Mrs Sophie Perry on 23/02/2016 00:10.

Job Title/Post:	Trainee Clinical Psychologist
Organisation:	Betsi Cadwaladr University Health Board
Email:	psp4f1@bangor.ac.uk

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co−sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Mr Hefin Francis on 23/02/2016 12:47.

Job Title/Post:	School Manager for Psychology
Organisation:	Bangor University
Email:	h.francis@bangor.ac.uk

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Dr Mike Jackson on 23/02/2016 12:21.

Job Title/Post:	clinical psychologist
Organisation:	bcuhb
Email:	mike.jackson@wales.nhs.uk

Academic supervisor 2

This section was signed electronically by Dr Rudi Coetzer on 25/02/2016 10:55.

Job Title/Post:	Consultant Neuropsychologist & Head of NWBIS
Organisation:	Betsi Cadwaladr University Health Board NHS Wales
Email:	Rudi.Coetzer@wales.nhs.uk

Appendix III

Research Ethics Committee Amendments and Approval Letter

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service

Ariennir gan **Lywodraeth Cymru**
Funded by **Welsh Government**

Pwyllgor Moeseg Ymchwil Cymru 5
Wales Research Ethics Committee 5
Bangor

Clinical Academic Office
Ysbyty Gwynedd Hospital
Betsi Cadwaladr University Health Board
Bangor, Gwynedd
LL57 2PW

Telephone/ Facsimile: 01248 - 384.877
Email: Rossela.Roberts@wales.nhs.uk
Website : www.nres.nhs.uk

21 March 2016

Mrs Sophie Perry
North Wales Clinical Psychology Programme
43 College Road
Gwynedd
LL57 2DG psp4f1@bangor.ac.uk

Dear Mrs Perry,

Study title:	**An exploration of insight, executive function and psychological distress following acquired brain injury (ABI)**
REC reference:	**16/WA/0085**
IRAS project ID:	**194308**

The Research Ethics Committee reviewed the above application at the meeting held on 17 March 2016. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Dr Rossela Roberts, rossela.roberts@wales.nhs.uk
Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Amendments to study documentations (Participant Information Sheet)

1. The first paragraph should be re-phrased as an invitation to take part in a research study.

2. Participants should be informed that access to their medical notes may be required and explicit consent should be sought.

3. Arrangements made to deal with incidental disclosures should be detailed.

4. A Welsh language translation should be provided to participants

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS.

The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Summary of discussion at the meeting

Ethical issues raised by the Committee in private discussion, together with responses given by you when invited to join the meeting

The Chairman welcomed the applicants and introduced the Committee members.
The following issues were discussed:

Care and protection of research participants; respect for participants' welfare and dignity; data protection and confidentiality
The Committee discussed the respect for potential and enrolled research participants' welfare and dignity, the arrangements made to protect privacy through confidentiality and raised no issues.

Data protection & research participant's confidentiality
The information governance aspects of the study were discussed, where and for how long will data be stored, and clarified who will have access to the data.
The Committee concluded that the information about subjects be appropriately handled.
It was noted that participants should be informed that access to their medical notes may be required and explicit consent should be sought.
Arrangements should be made to deal with incidental disclosures.

Favourable risk benefit ratio; anticipated benefit/risks for research participants
The Committee discussed the anticipated benefits and potential risk for individual research participants, and whether the research team clearly identified them and took steps to minimise or eliminate the risk, hazards, discomfort, and distress and enhance potential benefits;
The Committee was satisfied that the risks to the research participant were considered proportionate to the benefits and the balance between risk and benefit equitable.
The applicant has suitably identified the risks and benefits and highlighted them in the information given to potential participants.
A query was raised in relation to the process in place to deal with sings of anxiety or depression.
You clarified that all participants would be well known to the Brain Injury Service and it is very unlikely that clinically significant sings of anxiety and depression would have gone unnoticed to the clinical service; however, if this should happen, patient's permission would be sought to refer this to the clinical care team.

Informed Consent process and the adequacy and completeness of participant information
The Committee discussed the provision of information to research participants about the

purpose of the research, its procedures, potential risks, benefits, and alternatives, and whether it includes all procedures as describe in the protocol.
A Welsh language version of the participant facing documentation should be provided to all participants.
The Committee noted that written informed consent is taken as part of a process - with participants having adequate time to consider the information, and opportunity to ask questions. The language used is understandable to the research participants, the information is clear as to what the participant consents to, and there is no inducement or coercion.
The Committee agreed that the procedures described in the protocol have been adequately addressed in the Information Sheet, but felt that minor amendments should be made to ensure that individuals understand the information and can make a voluntary informed decision to enrol and continue to participate
It was noted that the first paragraph needs re-phrasing to better clarify the purpose of the study.

The Chairman thanked you for your availability to speak to this submission and gave you an opportunity to ask questions. You did not raise any issues.
The Chairman confirmed that the Committee will deliberate and will be in touch shortly.

Other ethical issues were raised and resolved in preliminary discussion before your attendance at the meeting.

Based on the information provided, the Committee was satisfied with the following aspects of the research:

- Social or scientific value; scientific design and conduct of the study
- Recruitment arrangements and access to health information, and fair participant selection
- Favourable risk benefit ratio; anticipated benefit/risks for research participants
- Care and protection of research participants; respect for participants' welfare and dignity
- Informed consent process and the adequacy and completeness of participant information
- Suitability of the applicant and supporting staff
- Independent review
- Suitability of supporting information
- Other general issues
- Suitability of the summary of the research

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
REC Application Form [REC_Form_25022016]		25 February 2016
Research protocol or project proposal [Research Protocol_V1]	1	26 January 2016
Participant information sheet [PIS_V2]	2	17 February 2016
Participant consent form [Consent Form_V2]	2	17 February 2016
Summary CV for Chief Investigator (CI) [Sophie Perry]	-	-
Summary CV for supervisor (student research) [Rudi Coetzer]	-	-
Summary CV for supervisor (student research) [Mike Jackson]	-	-
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UMAL insurance certificate]	-	20 July 2015

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

No declarations of interest have been made in relation to this application

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

16/WA/0085	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Rossela Roberts

Dr Philip Wayman White, MBChB, FRCGP
Chair
E-mail: rossela.roberts@wales.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

SL-AR2 After ethical review - research oth

Copy to:

Sponsor:
Mr Hefin Francis
School Manager
School of Psychology
Bangor University
Brigantia Building, Penrallt Road,
Bangor, Gwynedd, LL52 2AS h.francis@bangor.ac.uk

Academic Supervisor:
Dr Rudi Coetzer
School of Psychology
Bangor University
Brigantia Building, Penrallt Road,
Bangor, Gwynedd, LL52 2AS rudi.coetzer@wales.nhs.uk

R&D Office:
Miss Debra Slater
Clinical Academic Office
Betsi Cadwaladr University Health Board
Ysbyty Gwynedd Hospital
Bangor, Gwynedd, LL57 2PW debra.slater@wales.nhs.uk

Wales Research Ethics Committee 5

Attendance at Committee meeting on 17 March 2016

Committee Members

Name	*Profession*	*Capacity*	*Present*
Dr Karen BE Addy	Clinical Psychologist	Expert	No
Dr Swapna Alexander	Consultant Physician	Expert	Yes
Mrs Kathryn Chester	Research Nurse	Expert	Yes
Ms Geraldine Jenson	Retired College Vice-Principal	Lay +	Yes
Mr Eliezer Lichtenstein	Student	Lay +	Yes
Dr Mark G Lord	Consultant Pathologist	Expert	Yes
Dr Pamela A Martin-Forbes	WCRW Research Officer	Expert	No
Dr Paul G Mullins	Reader, MRI Physicist	Lay +	Yes
Mr Vishwanath Puranik	Associate Specialist ENT Surgeon	Expert	Yes
Mrs Lynn C Roberts	Matron, Emergency Department	Expert	Yes
Dr Judith L Roberts	Research Officer	Expert	No
Mrs Rachel L Roberts-Jones	Student	Lay +	Yes
Dr Jason D Walker	Consultant Anaesthetist (Vice-Chairman)	Expert	Yes
Dr Philip W White	General Practitioner (Chairman)	Expert	Yes
Ms Sydna A Williams	Lecturer	Lay +	Yes

In attendance

Name	*Position (or reason for attending)*
Dr Rossela Roberts	Clinical Governance Officer / RES Manager

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

Pwyllgor Moeseg Ymchwil Cymru 5
Wales Research Ethics Committee 5
Bangor

Clinical Academic Office
Ysbyty Gwynedd Hospital
Betsi Cadwaladr University Health Board
Bangor, Gwynedd
LL57 2PW

Telephone/ Facsimile: 01248 - 384.877
Email: Rossela.Roberts@wales.nhs.uk
Website : www.nres.nhs.uk

11 April 2016

Mrs Sophie Perry
North Wales Clinical Psychology Programme
43 College Road
Gwynedd
LL57 2DG psp4f1@bangor.ac.uk

Dear Mrs Perry,

Study title:	**An exploration of insight, executive function and psychological distress following acquired brain injury (ABI)**
REC reference:	**16/WA/0085**
IRAS project ID:	**194308**

Thank you for your letter of 11 April 2016. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 21 March 2016

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant consent form [Consent Form_V3]	3	07 April 2016
Participant information sheet (PIS) [PIS_V3]	3	07 April 2016

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
REC Application Form [REC_Form_25022016]		25 February 2016
Research protocol or project proposal [Research Protocol_V1]	1	26 January 2016
Participant information sheet [PIS_V3]	3	07 April 2016
Participant consent form [Consent Form_V3]	3	07 April 2016
Summary CV for Chief Investigator (CI) [Sophie Perry]	-	-
Summary CV for supervisor (student research) [Rudi Coetzer]	-	-
Summary CV for supervisor (student research) [Mike Jackson]	-	-
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UMAL insurance certificate]	-	20 July 2015

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

16/WA/0085	**Please quote this number on all correspondence**

Yours sincerely

Rossela Roberts

Dr Rossela Roberts
Research Ethics Service Manager

E-mail: rossela.roberts@wales.nhs.uk

Copy to: Sponsor: Mr Hefin Francis
School Manager
School of Psychology
Bangor University
Brigantia Building, Penrallt Road,
Bangor, Gwynedd, LL52 2AS h.francis@bangor.ac.uk

Academic Supervisor: Dr Rudi Coetzer
School of Psychology
Bangor University
Brigantia Building, Penrallt Road,
Bangor, Gwynedd, LL52 2AS rudi.coetzer@wales.nhs.uk

R&D Office: Miss Debra Slater
Clinical Academic Office
Betsi Cadwaladr University Health Board
Ysbyty Gwynedd Hospital
Bangor, Gwynedd, LL57 2PW debra.slater@wales.nhs.uk

Appendix IV

Research & Development Amendment and Approval Letters

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Betsi Cadwaladr University Health Board

Panel Arolygu Mewnol Y&D - Canolog
R&D Internal Review Panel

Betsi Cadwaladr University Health Board
Ysbyty Gwynedd
Clinical Academic Office
Bangor, Gwynedd
LL57 2PW

Chairman/Cadeirydd – Dr Nefyn Williams PhD, FRCGP
Email: rossela.roberts@wales.nhs.uk
debra.slater@wales.nhs.uk
sion.lewis@wales.nhs.uk
Tel/Fax: 01248 384 877

Mrs. Sophie Perry
Trainee Clinical Psychologist
North Wales Clinical Psychology Programme
School of Psychology, Bangor University
Bangor, Gwynedd
LL57 2DG psp4f1@bangor.ac.uk

13th June 2016

Dear Mrs. Sophie Perry

Re: Confirmation that R&D governance checks are complete / R&D approval granted

Study Title	**The psychological and cognitive correlates of insight following ABI.**
IRAS reference	194308
REC reference	16/WA/0085

The above research project was reviewed at the meeting of the BCUHB R&D Internal Review Panel

The Panel is satisfied with the scientific validity of the project, the risk assessment, the review of the NHS cost and resource implications and all other research management issues pertaining to the revised application.

The Internal Review Panel is pleased to confirm that all governance checks are now complete and to grant approval to proceed at Betsi Cadwaladr University Health Board sites as described in the application.

The documents reviewed and approved are listed below:

Document:	Version:	Date:
R&D Form	V5.3.0	19/04/2016
SSI Form	V5.3.0	26/04/2016
Research protocol	V1	26/01/2016
Participant Information Sheet	V3	07/04/2016
Consent Form	V3	07/04/2016
Awareness questionnaire - Clinican	-	-
Awareness questionnaire – Patient	-	-
Trial Making Test (TMT) – parts A and B	-	-
WCST Record Booklet	-	-
Summary CV: Perry		26/01/2016
Summary CV: Jackson		2016
Summary CV: Croetzer		June 2015
Evidence of Insurance (UMAL)		Expires 31/07/2016
REC Favourable Opinion		11/04/2016

All research conducted at the Betsi Cadwaladr University Health Board sites must comply with the Research Governance Framework for Health and Social Care in Wales (2009). An electronic link to this document is provided on the BCUHB R&D WebPages. Alternatively, you may obtain a paper copy of this document via the R&D Office.

Attached you will find a set of approval conditions outlining your responsibilities during the course of this research. Failure to comply with the approval conditions will result in the withdrawal of the approval to conduct this research in the Betsi Cadwaladr University Health Board.

If your study is adopted onto the NISCHR Clinical Research Portfolio (CRP), it will be a condition of this NHS research permission, that the Chief Investigator will be required to regularly upload recruitment data onto the portfolio database. To apply for adoption onto the NISCHR CRP, please go to: http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=31979. Once adopted, NISCHR CRP studies may be eligible for additional support through the NISCHR Clinical Research Centre. Further information can be found at:http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=28571 and/or from your NHS R&D office colleagues.

To upload recruitment data, please follow this link:
http://www.crncc.nihr.ac.uk/about_us/processes/portfolio/p_recruitment.
Uploading recruitment data will enable NISCHR to monitor research activity within NHS organizations, leading to NHS R&D allocations which are activity driven. Uploading of recruitment data will be monitored by your colleagues in the R&D office. If you need any support in uploading this data, please contact debra.slater@wales.nhs.uk or sion.lewis@wales.nhs.uk

If you would like further information on any other points covered by this letter please do not hesitate to contact me.

On behalf of the Panel, may I take this opportunity to wish you every success with your research.

Yours sincerely,

Dr. Rossela Roberts, MICR, CSci
Clinical Governance Officer (R&D/Ethics)

Copy to:

On behalf of Sponsor:	Hefin Francis School of Psychology Brigantia Building, Penrallt Road, Bangor University, Bangor LL57 2AS h.francis@bangor.ac.uk
Academic Supervisors:	Dr Rudi Coetzer North Wales Brain Injury Service Colwyn Bay Hospital Hesketh Road Colwyn Bay LL29 8AY Rudi.Coetzer@wales.nhs.uk
	Dr Mike Jackson North Wales Clinical Psychology Programme 43 College Road, Bangor University Bangor LL57 2DG Mike.Jackson@bangor.ac.uk

Appendix V

Participant Consent Form – English

Consent Form V3
07/04/2016
Bangor University Ethics Application Number: 15617
Wales REC 5 Ref: 16/WA/0085

Participant Identification Number:

Consent Form

Study title: An exploration into the psychological and cognitive correlates of self awareness in post-acute traumatic brain injury.

Name of researcher: Sophie Perry, Trainee Clinical Psychologist
Supervised by: Dr Rudi Coetzer, Consultant Clinical Neuropsychologist
Dr Mike Jackson, Consultant Clinical Psychologist

Please initial box

1. I confirm that I have read the Participant Information Sheet dated 07/04/2016 (Version 3) for the above study. ☐
2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my care anywhere in the NHS being affected. ☐
4. I understand that the information collected about me may be used to support other research in the future at the NWBIS. ☐
5. I agree to the researcher (Sophie Perry) accessing my medical notes for information about my brain injury ☐
6. I agree to take part in the above study ☐

Name of Participant	Date	Signature
Name of Person Taking Consent	Date	Signature

Appendix VI

Participant Consent Form – Welsh

Consent Form V3
07/04/2016
Bangor University Ethics Application Number: 15617
Wales REC 5 Ref: 16/WA/0085

Rhif Adnabod Cyfranogwr :

Ffurflen Gydsynio

Teitl yr astudiaeth: Archwiliad i gydberthnasau seicolegol a gwybyddol hunanymwybyddiaeth mewn anaf trawmatig ôl-lym i'r ymennydd.

Enw'r ymchwilydd: Sophie Perry, Seicolegydd Clinigol dan Hyfforddiant
Dan oruchwyliaeth: Dr Rudi Coetzer, Niwroseicolegydd Clinigol Ymgynghorol
Dr Mike Jackson, Seicolegydd Clinigol Ymgynghorol

Llofnodwch y bocs

1. Cadarnhaf fy mod wedi darllen y daflen wybodaeth i gyfranogwyr dyddiedig 07/04/2016 (Fersiwn 3) ar gyfer yr astudiaeth uchod. ☐
2. Rwyf wedi cael cyfle i ystyried y wybodaeth a gofyn cwestiynau ac wedi cael atebion boddhaol iddynt. ☐
3. Deallaf fy mod yn cymryd rhan o'm gwirfodd, a bod gennyf hawl i dynnu'n ôl ar unrhyw adeg, heb roi unrhyw reswm, a heb i hynny effeithio ar fy ngofal gan y GIG. ☐
4. Deallaf y gall y wybodaeth a gesglir amdanaf gael ei defnyddio i gefnogi ymchwil arall yn y dyfodol yng Ngwasanaeth Anaf i'r Ymennydd Gogledd Cymru (NWBIS). ☐
5. Rwy'n caniatáu i'r ymchwilydd (Sophie Perry) weld fy nodiadau meddygol i gael gwybodaeth am yr anaf i'm hymennydd ☐
6. Rwy'n cytuno i gymryd rhan yn yr astudiaeth uchod. ☐

Enw'r cyfranogwr	Dyddiad	Llofnod
Enw'r sawl sy'n cymryd cydsyniad	Dyddiad	Llofnod

Appendix VII

Participant Information Sheet – English

Participant Information Sheet

Dear Potential Participant,

Thank you for your interest in our research, we would like to invite you to take part and we hope that this document answers any questions that you may have.

Sophie Perry is a Trainee Clinical Psychologist. She is completing a three year Doctoral course to become a Clinical Psychologist. As part of her training she is conducting the research detailed below, supervised by Dr Rudi Coetzer, Consultant Clinical Neuropsychologist. We would like to invite you to read the following information about the research and Sophie will phone you at an agreed time to answer any further questions that you may have.

Study title: An exploration into the psychological and cognitive correlates of self awareness in post-acute traumatic brain injury.

What is the purpose of the research?

We are interested in better understanding how much awareness people have of any difficulties or changes in their thinking skills, after a brain injury. There is some research published in the area but it is not clear why some people are very aware of changes in their abilities, and why a considerable proportion of people with a brain injury are not. It is possible that awareness could be linked to psychological distress (e.g. low mood or anxiety), and/or changes in executive function, which is an umbrella term for thinking skills such as planning, organising, initiating, monitoring and changing behaviour.

Reduced awareness following a brain injury can be distressing for the person with the brain injury and their families. If we can understand better the process behind changes in awareness, we could tailor therapy to help people more effectively following a brain injury.

Why have I been invited to participate?

You have been invited to participate because you have had a brain injury which was at least one year ago, and you have come to the North Wales Brain Injury Service (NWBIS) for an assessment and / or therapy.

What would taking part involve?

In the first instance the researcher, Sophie Perry will contact you approximately one week after you receive this information sheet by telephone to answer any questions you may have about taking part.

If you are interested in taking part, she will then arrange to meet with you in person, either at the NWBIS, your GP surgery or at home (which ever you would prefer). If you prefer to hold the meeting at your home, as standard we would suggest that a family member or carer be present to ensure your and the researcher's safety. The appointment will last no more than 2 hours but we could meet for two shorter appointments if you wish. Travel costs will be reimbursed.

In the appointment you will be asked to complete some paper and pencil type tasks to look at your executive function skills and to fill in a few questionnaires to ask about your mood, and any changes you may have noticed in your thinking skills. If it is ok with you, I will also ask someone at the NWBIS who knows you to fill out the same questionnaire so we can compare the two. With your permission, I will also collect information about your brain injury from your patient file at the NWBIS and your medical notes.

Anything with your name on or any other way of identifying you will be kept locked safely at the NWBIS. The information used for the study will be completely anonymous so no-one will know it is yours. With your permission, the annonymised data will be entered onto a larger database kept securely at the NWBIS to benefit larger projects in the future.

Will I get the results of the tasks I take part in?

If you would like your results from the tasks you complete for the study you can request them and they will be fed back to you by Sophie Perry or Dr Rudi Coetzer. After the study has been completed in the spring of 2017, Sophie Perry will also write to you with a newsletter to let you know what we have found in the study.

What if I don't want to take part, or I change my mind?

It is completely up to you whether you decide to take part or not, and it will have absolutely no effect on the care you receive from the NWBIS.

You can change your mind at any time, you can also ask for your data to be removed after you have participated in the study if you wish.

What will I get out of it?

There is no direct benefit to you for taking part in this study but your participation has the potential to benefit people in the future and the therapy they receive following a brain injury.

Are there any disadvantages to taking part?

It is anticipated that the study will take up to about two hours of your time. There is a small possibility that you might find some of the tasks more difficult than you expected which can sometimes be frustrating or upsetting. You will also be asked to complete a questionnaire about how you are feeling which can very occasionally bring distressing feelings to the front of your mind. If this is the case for you we will encourage you to speak to your treating clinician at the NWBIS or your GP. In extreme circumstances we would ask your permission to write to your GP. If you decide you want to stop any of the tasks, at any time you can.

In the unlikely event that you were to tell the researcher something that made them very worried about your safety or the safety of someone else, they have a duty of care to share that information with other professionals to make sure that everyone is kept safe.

Who is funding and organising the research?

This research is organised and funded by the North Wales Clinical Psychology Programme, at Bangor University.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the Wales REC 5 Research Ethics Committee (Ref: 16/WA/0085).

What if something goes wrong?

If you have a concern about any aspect of this study, you should speak to the researcher, who will do their best to answer your questions. You should contact Sophie Perry on 07772 564 365, or email psp4f1@bangor.ac.uk. You can also contact Dr Rudi Coetzer, Consultant Neuropsychologist and Head of NWBIS on 01492 807770, or email Rudi.Coetzer@wales.nhs.uk

If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study please contact Mr Hefin Francis, who is the Bangor University contact for complaints regarding research, at the following address:

Mr Hefin Francis, School of Psychology Manager,
School of Psychology,
Brigantia Building,
Penrallt Road,
Gwynedd. LL57 2DG.

Tel: 01248 388 339
E-mail: h.francis@bangor.ac.uk

Thank you for taking the time to read this information sheet, I look forward to answering any questions you may have.

Kind regards,

Sophie Perry
Trainee Clinical Psychologist

Supervised by

Dr Rudi Coetzer
Consultant Clinical Neuropsychologist

Appendix VIII

Participant Information Sheet – Welsh

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Betsi Cadwaladr University Health Board

PRIFYSGOL BANGOR UNIVERSITY 1884

Taflen wybodaeth i rai sy'n cymryd rhan

Annwyl Gyfranogwr Posibl,

Diolch am eich diddordeb yn ein hymchwil. Hoffem eich gwahodd i gymryd rhan a gobeithiwn y bydd y ddogfen hon yn ateb unrhyw gwestiynau sydd gennych efallai.

Mae Sophie Perry yn Seicolegydd Clinigol dan Hyfforddiant. Mae'n gwneud cwrs doethur tair blynedd i ddod yn Seicolegydd Clinigol. Fel rhan o'i hyfforddiant clinigol, mae hi'n gwneud yr ymchwil a ddisgrifir isod, gan oruchwyliaeth Dr Rudi Coetzer, Niwroseicolegydd Clinigol Ymgynghorol. Hoffem eich gwahodd i ddarllen y wybodaeth ganlynol am yr ymchwil a bydd Sophie yn eich ffonio ar amser y cytunir arno i ateb unrhyw gwestiynau pellach fydd gennych.

Teitl yr astudiaeth: Archwiliad i gydberthynas seicolegol a gwybyddol hunanymwybyddiaeth mewn anaf trawmatig ôl-lym i'r ymennydd.

Beth yw pwrpas yr ymchwil?

Mae gennym ddiddordeb dod i ddeall yn well pa mor ymwybodol yw pobl o anawsterau neu newidiadau yn eu sgiliau meddwl ar ôl iddynt gael anaf i'r ymennydd. Mae peth ymchwil wedi'i chyhoeddi yn y maes ond nid yw'n glir pam fod rhai pobl yn llawer mwy ymwybodol o newidiadau yn eu galluoedd ar ôl cael anaf i'r ymennydd, a pham nad yw cyfran sylweddol o bobl yn ymwybodol o newidiadau o'r fath. Mae'n bosibl y gall ymwybyddiaeth fod yn gysylltiedig â thrallod seicolegol (e.e. iselder neu orbryder), ac/neu newidiadau mewn swyddogaethau gweithredu, sy'n derm cyffredinol am sgiliau meddwl fel cynllunio, trefnu, monitro a newid ymddygiad.

Gall lleihad mewn ymwybyddiaeth yn dilyn anaf i'r ymennydd fod yn drallodus i rai gydag anaf i'r ymennydd ac i'w teuluoedd. Os gallwn ddeall yn well y broses tu ôl i newidiadau mewn ymwybyddiaeth, gallem lunio therapi i helpu pobl yn fwy effeithiol yn dilyn anaf i'r ymennydd.

Pam y gofynnwyd imi gymryd rhan?

Rydych wedi cael gwahoddiad i gymryd rhan oherwydd i chi gael anaf i'r ymennydd o leiaf flwyddyn yn ôl, a'ch bod wedi dod at Wasanaeth i'r Ymennydd Gogledd Cymru (NWBIS) i gael asesiad ac/neu therapi.

Beth fydd cymryd rhan yn ei olygu?
Yn y lle cyntaf bydd yr ymchwilydd, Sophie Perry, yn cysylltu â chi ar y ffôn tua wythnos ar ôl i chi dderbyn y daflen wybodaeth hon i ateb unrhyw gwestiynau fydd gennych ynghylch cymryd rhan.

Os bydd gennych ddiddordeb cymryd rhan wedyn, bydd yn trefnu i gyfarfod â chi wyneb yn wyneb, naill ai yn NWBIS, yn eich meddygfa leol neu yn eich cartref (pa un bynnag sydd orau gennych). Os byddai'n well gennych gyfarfod yn eich cartref, byddem yn awgrymu fel mater o drefn bod aelod o'ch teulu neu ofalwr yn bresennol i sicrhau eich diogelwch chi a'r ymchwilydd. Ni fydd yr apwyntiad yn para mwy na dwy awr, ond gellir ei rannu'n ddau apwyntiad byrrach os byddai'n well gennych. Telir costau teithio.

Yn ystod yr apwyntiad gofynnir i chi wneud nifer o dasgau ar bapur i edrych ar eich sgiliau swyddogaeth weithredu a llenwi ychydig o holiaduron sy'n gofyn cwestiynau am eich hwyliau, ac unrhyw newidiadau rydych wedi sylwi arnynt yn eich sgiliau meddwl. Os yw hynny'n iawn efo chi, byddaf hefyd yn gofyn i rywun o NWBIS sy'n eich adnabod i lenwi'r un holiadur fel y gallwn gymharu'r ddau. Gyda'ch caniatâd, byddaf hefyd yn casglu gwybodaeth am eich anaf ymennydd o'ch ffeil claf yn y NWBIS ac o'ch nodiadau meddygol.

Caiff unrhyw beth gyda'ch enw arno, neu unrhyw ffordd arall o ddangos pwy ydych, ei gadw'n ddiogel dan glo yn y NWBIS. Bydd y wybodaeth a ddefnyddir ar gyfer yr astudiaeth yn hollol ddienw fel na fydd neb yn gwybod ei bod yn sôn amdanoch chi. Gyda'ch caniatâd, caiff data dienw eu rhoi mewn cronfa ddata fwy a gedwir yn ddiogel yn y NWBIS er budd projectau mwy yn y dyfodol.

A fyddaf yn cael canlyniadau'r tasgau y byddaf yn eu gwneud?
Os hoffech gael eich canlyniadau o'r tasgau y byddwch yn eu gwneud i'r astudiaeth, gellwch wneud cais amdanynt a bydd Sophie Perry neu Dr Rudi Coetzer yn eu hanfon atoch. Ar ôl i'r astudiaeth gael ei gorffen yng ngwanwyn 2017, bydd Sophie Perry hefyd yn anfon cylchlythyr atoch i roi gwybod i chi beth rydym wedi'i ddarganfod yn yr astudiaeth.

Beth os nad ydw i eisiau cymryd rhan neu os byddaf yn newid fy meddwl?
Chi yn unig sydd i benderfynu a ydych am gymryd rhan neu beidio, ac ni fydd yn cael unrhyw effaith o gwbl ar y gofal rydych yn ei gael gan y NWBIS.

Gellwch newid eich meddwl ar unrhyw adeg a hefyd ofyn am i'ch data gael ei dynnu o'r astudiaeth ar ôl i chi gymryd rhan ynddi.

Beth fydd y manteision i mi?
Nid oes unrhyw fantais uniongyrchol i chi o gymryd rhan yn yr astudiaeth ond mae'n bosib y bydd eich cyfranogiad o fudd i bobl yn y dyfodol a'r therapi y byddant yn ei chael yn dilyn anaf i'r ymennydd.

A oes unrhyw anfanteision o gymryd rhan?
Rhagwelir y bydd yr astudiaeth yn cymryd tua dwy awr o'ch amser. Mae yna bosibilrwydd bach y gallech weld rhai o'r tasgau'n fwy anodd nag roeddech wedi ei ddisgwyl, a all weithiau fod yn rhwystredig neu'n annifyr. Gofynnir i chi hefyd lenwi holiadur ynghylch sut rydych yn teimlo a gall hynny'n achlysurol iawn ddod â theimladau annymunol i flaen eich cof. Os bydd hynny'n digwydd i chi, byddwn yn eich annog i siarad â'r clinigwr sy'n eich trin yn y NWBIS neu gyda'ch meddyg teulu. Mewn amgylchiadau eithriadol byddwn yn gofyn eich caniatâd i ysgrifennu at eich meddyg teulu. Os ydych eisiau rhoi'r gorau i unrhyw rai o'r tasgau ar unrhyw adeg fe ellwch wneud hynny.

Pe baech yn dweud rhywbeth wrth yr ymchwilydd a fyddai'n ei gwneud yn boenus ynghylch eich diogelwch neu ddiogelwch rhywun arall, mae ganddi ddyletswydd gofal i rannu'r wybodaeth honno gyda gweithwyr proffesiynol eraill i wneud yn siŵr fod pawb yn cael ei gadw'n ddiogel.

Pwy sy'n ariannu a threfnu'r ymchwil?
Trefnir ac ariannir yr astudiaeth hon gan Raglen Seicoleg Glinigol Gogledd Cymru, ym Mhrifysgol Bangor.

Pwy sydd wedi adolygu'r astudiaeth?
Edrychir ar bob ymchwil yn y GIG gan grŵp annibynnol o bobl, sef pwyllgor moeseg ymchwil, i warchod eich buddiannau. Mae'r astudiaeth hon wedi'i hadolygu a'i chymeradwyo gan Bwyllgor Moeseg Ymchwil Cymru (Cyf: 16/WA/0025).

Beth os aiff rhywbeth o'i le?
Os ydych yn bryderus ynghylch unrhyw agwedd ar yr astudiaeth hon, dylech siarad â'r ymchwilydd a fydd yn gwneud ei gorau i ateb eich cwestiynau. Dylech gysylltu â Sophie Perry ar 07772 564 365, neu e-bost psp4f1@bangor.ac.uk. Gellwch hefyd gysylltu â Dr Rudi Coetzer, Niwroseicolegydd Ymghyngorol a Phennaeth NWBIS ar 01492 807770, neu e-bostiwch Rudi.Coetzer@wales.nhs.uk

Os ydych yn parhau i fod yn anhapus am yr astudiaeth ac/neu yn dymuno gwneud cwyn am unrhyw agwedd ar y ffordd y cawsoch eich gwahodd neu eich trin yn ystod yr astudiaeth

hon, cysylltwch â Mr Hefin Francis, sef cyswllt Prifysgol Bangor ar gyfer cwynion sydd yn ymwneud ag astudiaethau, yn y cyfeiriad canlynol:

Mr Hefin Francis, Rheolwr yr Ysgol Seicoleg,
Ysgol Seicoleg,
Adeilad Brigantia,
Ffordd Penrallt,
Gwynedd, LL57 2DG.

Ffôn: 01248 388 339
E-bost: h.francis@bangor.ac.uk

Diolch i chi am roi'r amser i ddarllen y daflen wybodaeth hon. Edrychaf ymlaen at ateb unrhyw gwestiynau fydd gennych chi.

Yn gywir,

Sophie Perry
Seicolegydd Clinigol dan Hyfforddiant

Dan oruchwyliaeth:

Dr Rudi Coetzer
Niwroseicolegydd Clinigol

Appendix IX

Awareness Questionnaire (AQ)

Awareness Questionnaire
Patient Form

Name:_____ Patient #:_____ Date:_____

1	2	3	4	5
much worse	a little worse	about the same	a little better	much better

____ 1. How good is your ability to live independently now as compared to before your injury?

____ 2. How good is your ability to manage your money now as compared to before your injury?

____ 3. How well do you get along with people now as compared to before your injury?

____ 4. How well can you do on tests that measure thinking and memory skills now as compared to before your injury?

____ 5. How well can you do the things you want to do in life now as compared to before your injury?

____ 6. How well are you able to see now as compared to before your injury?

____ 7. How well can you hear now as compared to before your injury?

____ 8. How well can you move your arms and legs now as compared to before your injury?

____ 9. How good is your coordination now as compared to before your injury?

____ 10. How good are you at keeping up with the time and date and where you are now as compared to before your injury?

____ 11. How well can you concentrate now as compared to before your injury?

____ 12. How well can you express your thoughts to others now as compared to before your injury?

____ 13. How good is your memory for recent events now as compared to before your injury?

1	2	3	4	5
much worse	a little worse	about the same	a little better	much better

____ 14. How good are you at planning things now as compared to before your injury?

____ 15. How well organized are you now as compared to before your injury?

____ 16. How well can you keep your feelings in control now as compared to before your injury?

____ 17. How well adjusted emotionally are you now as compared to before your injury?

Awareness Questionnaire
Clinician Form

Clinician Name:_____ Date:_____

Patient:_____ Patient #:_____

1	2	3	4	5
much worse	a little worse	about the same	a little better	much better

____ 1. How good is the patient's ability to live independently now as compared to before his/her injury?

____ 2. How good is the patient's ability to manage his/her money now as compared to before his/her injury?

____ 3. How well does the patient get along with people now as compared to before his/her injury?

____ 4. How well can the patient do on tests that measure thinking and memory skills now as compared to before his/her injury?

____ 5. How well can the patient do the things he/she wants to do in life now as compared to before his/her injury?

____ 6. How well is the patient able to see now as compared to before his/her injury?

____ 7. How well can the patient hear now as compared to before his/her injury?

____ 8. How well can the patient move his/her arms and legs now as compared to before his/her injury?

____ 9. How good is the patient's coordination now as compared to before his/her injury?

____ 10. How good is the patient at keeping up with the time and date and where he/she is now as compared to before his/her injury?

1	2	3	4	5
much worse	a little worse	about the same	a little better	much better

____ 11. How well can the patient concentrate now as compared to before his/her injury?

____ 12. How well can the patient express his/her thoughts to others now as compared to before his/her injury?

____ 13. How good is the patient's memory for recent events now as compared to before his/her injury?

____ 14. How good is the patient at planning things now as compared to before his/her injury?

____ 15. How well organized is the patient now as compared to before his/her injury?

____ 16. How well can the patient keep his/her feelings in control now as compared to before his/her injury?

____ 17. How well adjusted emotionally is the patient now as compared to before his/her injury?

1	2	3	4	5
completely	severely	moderately	minimally	not at all

_____18. To what extent is the patient's accurate self-awareness impaired by his/her brain injury?

Appendix X

Hospital Anxiety and Depression Scales (HADS)

Hospital Anxiety and Depression Scale (HADS)

Instructions: Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he or she will be able to help you more. This questionnaire is designed to help your doctor know how you feel. Read each item and circle the reply which comes closest to how you have been feeling in the past week. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out response.

I feel tense or 'wound up':	**A**
Most of the time	3
A lot of the time	2
Time to time, occasionally	1
Not at all	0

I feel as if I am slowed down:	**D**
Nearly all of the time	3
Very often	2
Sometimes	1
Not at all	0

I still enjoy the things I used to enjoy:	**D**
Definitely as much	0
Not quite so much	1
Only a little	2
Not at all	3

I get a sort of frightened feeling like 'butterflies in the stomach':	**A**
Not at all	0
Occasionally	1
Quite often	2
Very often	3

I get a sort of frightened feeling like something awful is about to happen:	**A**
Very definitely and quite badly	3
Yes, but not too badly	2
A little, but it doesn't worry me	1
Not at all	0

I have lost interest in my appearance:	**D**
Definitely	3
I don't take as much care as I should	2
I may not take quite as much care	1
I take just as much care as ever	0

I can laugh and see the funny side of things:	**D**
As much as I always could	0
Not quite so much now	1
Definitely not so much now	2
Not at all	3

I feel restless as if I have to be on the move:	**A**
Very much indeed	3
Quite a lot	2
Not very much	1
Not at all	0

Worrying thoughts go through my mind:	**A**
A great deal of the time	3
A lot of the time	2
From time to time but not too often	1
Only occasionally	0

I look forward with enjoyment to things:	**D**
A much as I ever did	0
Rather less than I used to	1
Definitely less than I used to	3
Hardly at all	2

I feel cheerful:	**D**
Not at all	3
Not often	2
Sometimes	1
Most of the time	0

I get sudden feelings of panic:	**A**
Very often indeed	3
Quite often	2
Not very often	1
Not at all	0

I can sit at ease and feel relaxed:	**A**
Definitely	0
Usually	1
Not often	2
Not at all	3

I can enjoy a good book or radio or TV programme:	**D**
Often	0
Sometimes	1
Not often	2
Very seldom	3

Adapted from: Zigmond, A. S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatr Scand,67*(6), 361-370.

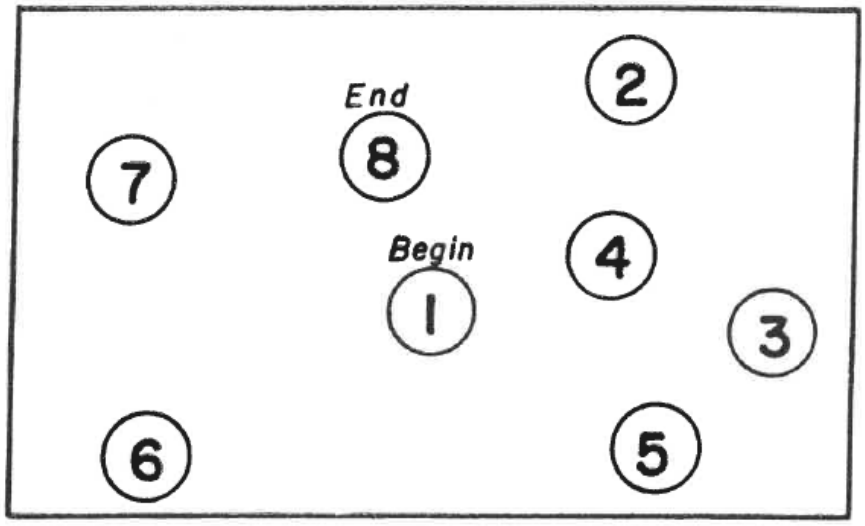
Appendix XI

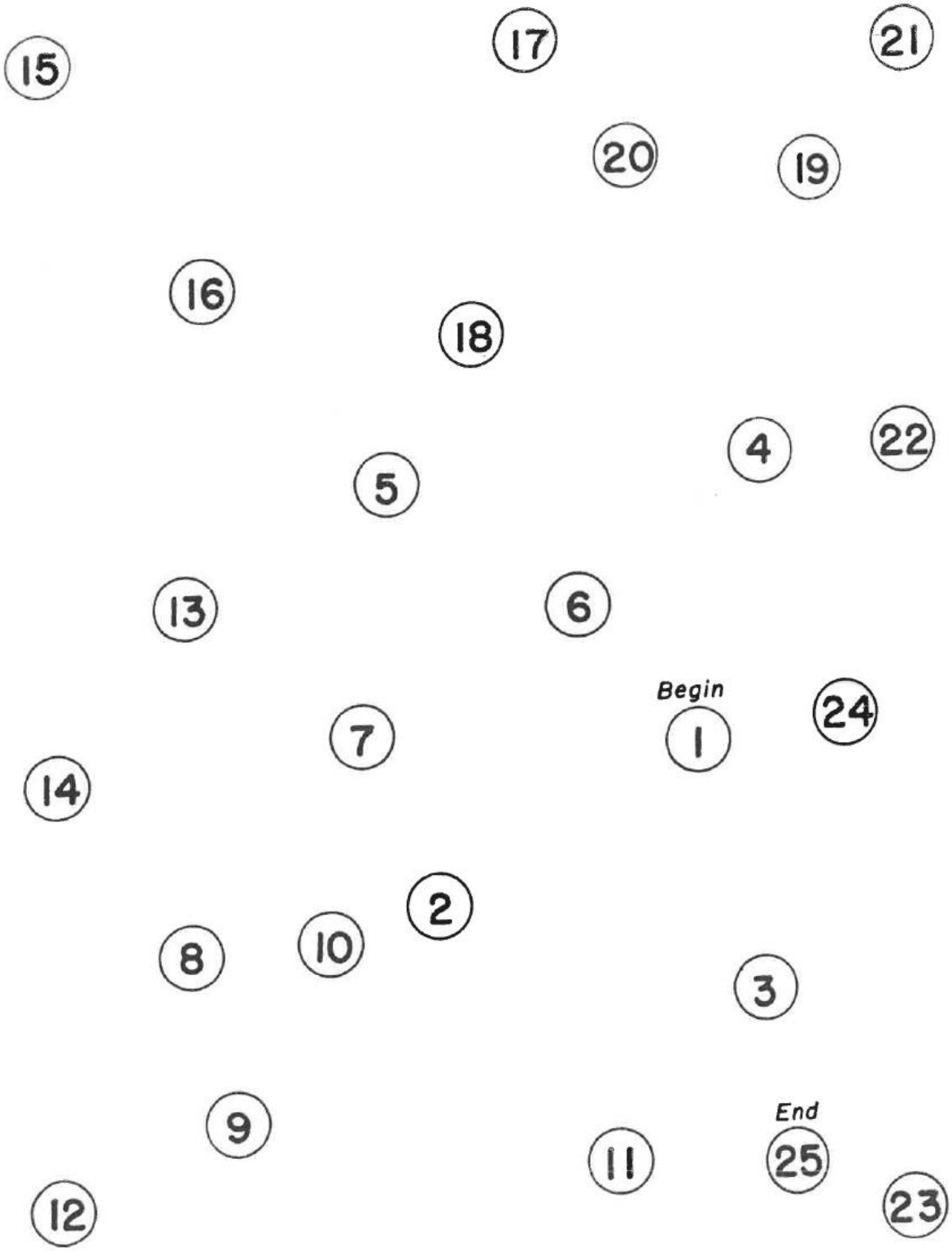
Trail Making Task A&B (TMT)

TRAIL MAKING

Part A

SAMPLE

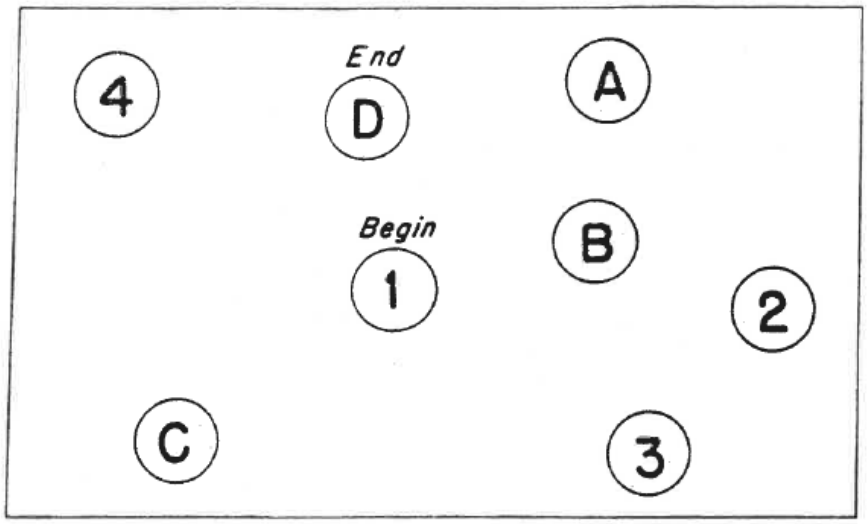


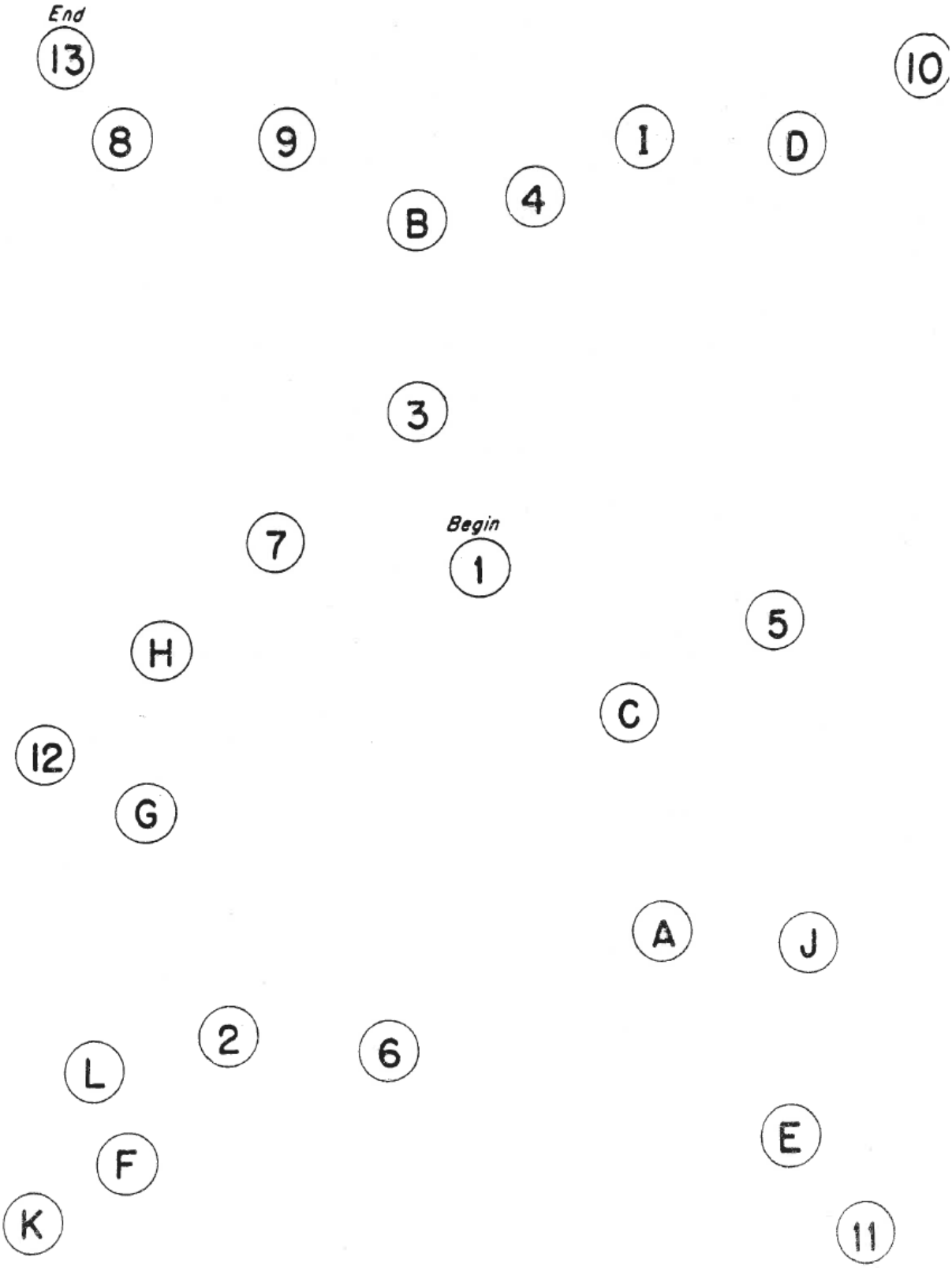

15
17
21
20
19
16
18
4
22
5
13
6
Begin
24
7
1
14
2
8
10
3
9
End
11
25
12
23

TRAIL MAKING

Part B

SAMPLE




End
13
10
8
9
1
D
4
B
3
7
Begin
1
5
H
C
12
G
A
J
2
6
L
E
F
K
11

Appendix XII

Wisconsin Card Sorting Test (WCST) - Record Form

WCST Record Booklet

Name _____ Test Date ____ / ____ / ____ (year / month / day)

ID # _____ Birth Date ____ / ____ / ____ (year / month / day)

Gender _____ Race _____ Handedness _____ Age _____

Occupation _____ Education _____

Examiner _____

Referral Information

Referral Question _____

Background Information/Presenting Complaints _____

Current Medications/Dosage _____

Behavioral Observations _____

TESTING SITUATION

Rapport	Cooperation	Effort on Test
☐ Excellent	☐ Excellent	☐ Excellent
☐ Good	☐ Adequate	☐ Adequate
☐ Fair	☐ Variable	☐ Fair
☐ Poor	☐ Resistant	☐ Variable
	☐ Noncompliant	☐ Poor

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CATEGORY SEQUENCE: C F N C F N

___ 1. C F N O	___ 33. C F N O	___ 1. C F N O	___ 33. C F N O
___ 2. C F N O	___ 34. C F N O	___ 2. C F N O	___ 34. C F N O
___ 3. C F N O	___ 35. C F N O	___ 3. C F N O	___ 35. C F N O
___ 4. C F N O	___ 36. C F N O	___ 4. C F N O	___ 36. C F N O
___ 5. C F N O	___ 37. C F N O	___ 5. C F N O	___ 37. C F N O
___ 6. C F N O	___ 38. C F N O	___ 6. C F N O	___ 38. C F N O
___ 7. C F N O	___ 39. C F N O	___ 7. C F N O	___ 39. C F N O
___ 8. C F N O	___ 40. C F N O	___ 8. C F N O	___ 40. C F N O
___ 9. C F N O	___ 41. C F N O	___ 9. C F N O	___ 41. C F N O
___ 10. C F N O	___ 42. C F N O	___ 10. C F N O	___ 42. C F N O
___ 11. C F N O	___ 43. C F N O	___ 11. C F N O	___ 43. C F N O
___ 12. C F N O	___ 44. C F N O	___ 12. C F N O	___ 44. C F N O
___ 13. C F N O	___ 45. C F N O	___ 13. C F N O	___ 45. C F N O
___ 14. C F N O	___ 46. C F N O	___ 14. C F N O	___ 46. C F N O
___ 15. C F N O	___ 47. C F N O	___ 15. C F N O	___ 47. C F N O
___ 16. C F N O	___ 48. C F N O	___ 16. C F N O	___ 48. C F N O
___ 17. C F N O	___ 49. C F N O	___ 17. C F N O	___ 49. C F N O
___ 18. C F N O	___ 50. C F N O	___ 18. C F N O	___ 50. C F N O
___ 19. C F N O	___ 51. C F N O	___ 19. C F N O	___ 51. C F N O
___ 20. C F N O	___ 52. C F N O	___ 20. C F N O	___ 52. C F N O
___ 21. C F N O	___ 53. C F N O	___ 21. C F N O	___ 53. C F N O
___ 22. C F N O	___ 54. C F N O	___ 22. C F N O	___ 54. C F N O
___ 23. C F N O	___ 55. C F N O	___ 23. C F N O	___ 55. C F N O
___ 24. C F N O	___ 56. C F N O	___ 24. C F N O	___ 56. C F N O
___ 25. C F N O	___ 57. C F N O	___ 25. C F N O	___ 57. C F N O
___ 26. C F N O	___ 58. C F N O	___ 26. C F N O	___ 58. C F N O
___ 27. C F N O	___ 59. C F N O	___ 27. C F N O	___ 59. C F N O
___ 28. C F N O	___ 60. C F N O	___ 28. C F N O	___ 60. C F N O
___ 29. C F N O	___ 61. C F N O	___ 29. C F N O	___ 61. C F N O
___ 30. C F N O	___ 62. C F N O	___ 30. C F N O	___ 62. C F N O
___ 31. C F N O	___ 63. C F N O	___ 31. C F N O	___ 63. C F N O
___ 32. C F N O	___ 64. C F N O	___ 32. C F N O	___ 64. C F N O

SCORING AREA

	Raw score	Standard score	*T* score	Percentile score
Number of Trials Administered				
Total Number Correct				
Total Number of Errors				
Percent Errors				
Perseverative Responses				
Percent Perseverative Responses				
Perseverative Errors				
Percent Perseverative Errors				
Nonperseverative Errors				
Percent Nonperseverative Errors				
Conceptual Level Responses				
Percent Conceptual Level Responses				

	Raw score	Percentile range
Number of Categories Completed		
Trials to Complete First Category		
Failure to Maintain Set		
Learning to Learn		

Normative table _____

Learning to Learn Score Worksheet				
Category number	**Number of trials**	**Errors**	**Percent errors**	**Percent errors difference score**
1				
2				
3				
4				
5				
6				
			Average difference	

Word Counts

Thesis Abstract – 285 words

Chapter 1 – Meta-analysis and systematic literature review

Abstract – 161 words

Main text (including tables and figures) – 4856 words

References – 1900 words

Total – 6917 words

Chapter 2 – Empirical research paper

Abstract – 160 words

Main text (including tables and figures) – 4407 words

References – 1481 words

Total – 6048 words

Chapter 3 – Contributions to theory and clinical practice

Main text (including tables and figures) – 3082 words

References – 983 words

Total – 4065 words